HEALTH LITERACY IN TREATMENT ASSIGNMENT AND MEDICATION ADHERENCE: APPLICATION TO STABLE ANGINA PECTORIS

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ABSTRACT

Samuel T. Savitz: Health Literacy in Treatment Assignment and Medication Adherence: Application to Stable Angina Pectoris
(Under the direction of Sally C. Stearns)

Health literacy is a major determinant of health outcomes, spending, and hospital admissions. However, gaps in the literature remain on the relationship between health literacy and health behaviors. The objective of this dissertation was to assess the relationship between health literacy and key health behaviors for patients with stable angina pectoris. The dissertation had three aims: 1) evaluate the relationship between health literacy and treatment assignment: medication only, percutaneous coronary intervention (PCI), or coronary artery bypass grafting (CABG) surgery; 2) assess patient and clinician behavior during treatment planning conversations; and 3) evaluate the relationship between health literacy and adherence to anti-anginal medications for stable angina.

We used a 20 percent Medicare claims sample from 2007-2013 to evaluate the first and third aims. Health literacy was assessed using an area-based measure. Multinomial logistic regression was used to evaluate the relationship between health literacy and treatment assignment. Probit regression, inverse probability of treatment weighting, and two-stage residual inclusion were used to assess the relationship between health literacy and medication adherence. For the second aim, we used recorded patient-clinician encounters and questionnaire data from the PCI Choice Trial. In this data source, health literacy was assessed using a validated screening question.

Patients living in low health literacy areas had significantly higher utilization of medication only (3.3 percentage points) and lower utilization of CABG (-3.0 percentage points) compared to patients in high health literacy areas. This finding may be related to health literacy being a predictor of worse access to care. Low literacy was associated with greater decisional conflict among patients and may be a barrier in communication. The clinician and the setting in which the conversation took place may also be important determinants of communication quality. Low health literacy may act as barrier to patient-clinician communication. Living in low health literacy areas was also associated with significantly lower medication adherence when using the quartile specification of health literacy (-2.8 percentage points), but not the dichotomous specification. There was also strong evidence for selection into treatment assignment. The small magnitude of these findings do not support the use of health literacy to inform interventions to improve medication adherence.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

2SRI	Two-stage residual inclusion
ADI	Area deprivation index
CABG	Coronary artery bypass grafting surgery
HL	Health literacy
IPTW	Inverse probability of treatment weighting
IV	Instrumental variable
ME	Marginal effect
PCI	Percutaneous coronary intervention
SAP	Stable angina pectoris
SE	Standard error

CHAPTER 1. INTRODUCTION

1.1. Specific Aims

About a quarter of all Americans have poor health literacy.[1] This number is expected to grow in the coming years due to increases in the share and absolute numbers of elderly and individuals who speak English as a second language.[2] Poor health literacy is associated with worse access to care, quality of care, and health outcomes. The associations between health literacy and these outcomes have been documented for a wide array of conditions.[3] However, the existing literature does not adequately address the causal pathways of health literacy with treatment assignment and important patient behaviors such as medication adherence. Few studies have explored health literacy's impact on treatment assignment; the existing studies have been small and used non-generalizable populations.[4] Further, prior studies on the relationship between health literacy and medication adherence show mixed results.[3] Patient comprehension of treatment options and effectiveness will become even more important as medicine transitions towards patient-centered care and shared decision-making.

The treatment of stable angina pectoris (SAP) is a promising area for evaluating the association of health literacy with treatment assignment (i.e., treatment choice) and medication adherence. SAP is a common condition with over eight million cases in the US.[5] The high prevalence of stable angina means that the condition imposes a large public health burden. Treatment assignment (i.e., the treatment alternative that the patient receives after discussing treatment with their clinicians) depends heavily on patient preferences in addition to clinical presentation.[6] The most commonly used treatments for SAP are medical therapy (i.e. medications alone), percutaneous coronary intervention (PCI) with medical therapy, and coronary artery bypass grafting (CABG) surgery with medical therapy.[6] Medical therapy is the same for all groups and consists of beta-blockers, calcium channel blockers, long-acting nitrates, short-acting nitrates, and ranolazine.[6] The alternatives vary in terms of cost,[7,8] potential symptomatic benefit,[9-12] and type and risk of complications.[13,14] Patients with poor health literacy may find it more difficult to weigh the risks and benefits of alternative treatments and to make an informed choice. Many of the risk factors associated with SAP (advanced age,[15] lower socioeconomic status,[16] and minority status[5]) are also associated with lower health literacy.[1,17] Two prior studies analyzed how poor comprehension of the advantages and disadvantages of treatment alternatives affects treatment selection for SAP.[18,19] The studies found that many patients who received PCI erroneously believed that the procedure would decrease their risk of death or myocardial infarction (MI) relative to medication therapy alone. This finding suggests that current patient-physician interactions are not resulting in informed decision making.[19] For medication adherence, no identified studies have assessed health literacy and medication adherence among patients with SAP. Nevertheless, medication is a key component of treatment for all treatment alternatives including PCI and CABG.[6]

The long-term goal of this research is to improve our understanding of how health literacy patient treatment for chronic conditions , particularly as it relates to treatment assignment and adherence. The objective of this study is to evaluate the association of health literacy with treatment assignment and medication adherence among Medicare patients with SAP. The central hypothesis is that living in a low health literacy area (as measured by a validated area-based measure[17,20]) will be associated with a higher probability of receiving more invasive treatment (PCI or CABG) and lower medication adherence. This research will enhance our understanding of how health literacy acts as a barrier to informed decision-making and improve patient adherence with assigned treatments.

Aim 1: Evaluate the association between an area-based measure for health literacy and assignment to more or less invasive treatment (i.e., medical therapy vs. PCI and CABG) for SAP. Hypothesis: Living in areas with low health literacy is associated with assignment of PCI and CABG over medication only. The analysis used multinomial logistic regression to analyze the relationship between treatment assignment and the health literacy measure using a 20 percent sample of Medicare claims data.

Aim 2: Evaluate clinician-patient interactions during treatment planning discussions for SAP. Hypothesis: The analysis evaluates potential barriers to effective clinician-patient communication including low health literacy and identify potential limitations in the claims data for Aim 1. The analysis used previously collected data from the PCI Choice Trial including audio and video recordings of clinician-patient encounters and patient questionnaires.

Aim 3: Evaluate the association of area-based health literacy with post-treatment medication adherence. Hypothesis: Living in areas with low health literacy is associated with worse medication adherence. Medication adherence is assessed as the proportion days covered for any of the following medications: beta-blockers, calcium channel blockers, long-acting nitrates, and ranolazine. The relationship with the health literacy measure was assessed using probit regression, inverse propensity score treatment weighting (IPTW), and two-stage residual inclusion.

The findings from this mixed-methods study on treatment assignment and health literacy supports interventions to improve patient comprehension and shared decision-making; similarly, results on patient adherence to medications informs interventions to improve medication adherence by identifying the role of health literacy.

1.2. Background

1.2.1. Overview of Stable Angina Pectoris

Angina is a symptom of coronary artery disease that involves pain or discomfort in the chest area. Coronary artery disease is caused by a buildup of plaque in coronary arteries. The plaque narrows and stiffens the arteries, which reduces the supply of blood to the heart and causes the angina symptoms. Angina is classified as 'stable' if the symptoms exhibit consistent patterns in terms of how long they last and when they occur.[21] Patients most commonly experience symptoms of SAP during physical exercise when the demand for blood is higher.[21] The risk factors for developing SAP include advanced age, high cholesterol, high blood pressure, smoking, being overweight or obese, lack of physical exercise, and poor diet.[21-23] SAP affects approximately eight million individuals in the US.[5]

1.2.2. Treatment for Stable Angina Pectoris

Patients with SAP have three main treatment options. The first option is medical therapy (for clarity, this alternative will be referred to as 'medication only'). Patients that receive medication only are prescribed anti-anginal medications, which include short-acting nitrates, long-acting nitrates, beta-blockers, calcium channel blockers, and ranolazine. Short-acting nitrates are taken as needed and the other medications are taken daily. The anti-anginal medications primary function is to manage the symptoms of angina.[6] If patients do not achieve sufficient reduction in their symptoms, then they may receive one of the other treatment alternatives.[6] The second alternative is percutaneous coronary intervention (PCI) plus medication. PCI is a non-invasive procedure in which a catheter is inserted into the blocked artery (or arteries) and a balloon on the end of the catheter is expanded to push the plaque against the walls of the artery. Usually, a stent is then positioned in the artery to keep it from re-narrowing. The stents are either bare metal stents (BMS) or drug-eluting stents (DES) that release a drug to prevent reblockage[6,21] The third alternative is coronary artery bypass graft (CABG) surgery. CABG is an invasive surgery in which the chest is opened to access the blocked artery. Then, healthy arteries or veins from other parts of the body are grafted to bypass the blocked or narrowed coronary arteries.[6,21] Patients who receive PCI or CABG also receive the same anti-anginal medications that patients in the medication only group receive.[6]

In addition to the anti-anginal medications, patients in all three treatment alternatives receive other medications to reduce the risk of MI, stroke, and death.[6] These medications include statins, ACE Inhibitors, antiplatelets, and anticoagulants.[6] Dual antiplatelet therapy (aspirin and clopidogrel) is especially important for patients who receive PCI with a BMS or DES.[14,24,25] For these patients, the dual antiplatelet therapy helps to prevent stent thrombosis,[14,24,25] which is a complication where a blood clot occurs in the artery that has had the stent implanted. Stent thrombosis often results in MI and death.[26] Given the importance of dual antiplatelet therapy for PCI, physicians are guided to not perform PCI if they do not believe the patient is likely to be adherent to dual antiplatelet therapy following the procedure.[6]

The treatment alternatives have key tradeoffs in terms of cost, symptom relief, and complications. Medication only is the least expensive alternative.[7] Patients who receive medication only generally have similar outcomes in terms of MI and death as patients who receive PCI or CABG.[27,28] However, these findings do not extend to the small subset of patients with left main disease who have often been excluded from trials.[6,27,28] Long-term symptom relief for patients who receive medication only is comparable to patients who receive PCI.[12] But, a greater proportion of patients who receive PCI experience short-term symptom relief than patients who receive medication only.[12] The recent ORBITA trial found no statistical difference in exercise time at six weeks between PCI plus medications and a sham procedure plus medications.[29] These findings raise the possibility that the difference in short-term relief may be partially due to a placebo effect from receiving a procedure. However, it is difficult to make definitive conclusions from this study because the population was relatively small and the main outcome (exercise time) was an intermediate outcome.[29] PCI is more expensive than mediation only[7] and less expensive than CABG.[8] The main complications for PCI are stent thrombosis[26] and restenosis, which is a reblockage of the artery that may require additional revascularization.[30] CABG is the most expensive and most invasive alternative.[8] CABG also leads to more complete reduction of symptoms than PCI or medication only.[9,11,31] CABG and PCI have similar outcomes for patients who have uncomplicated coronary artery disease. For patients with complex coronary artery disease, CABG reduces the risk of MI.[10,11] In addition, CABG has better outcomes for patients with diabetes[32,33] Due to the invasive nature of the procedure, CABG requires surgical recovery[34] and rehabilitation.[6] In contrast, patients who receive PCI typically have faster recovery[35] and it is increasingly common for PCI to be performed as an outpatient procedure.[36]

Prior research suggests that patients with SAP have difficulty understanding the tradeoffs between the treatment alternatives. A survey of patients after a treatment decision for SAP found that most patients who received PCI mistakenly believed that the PCI would reduce the risk of MI compared to medication only.[19] As noted, PCI generally does not reduce the risk of MI or death for SAP patients.[27] A separate survey of the physicians treating these patients found that most physicians correctly believed that the benefit of PCI relative to medication only would be limited to symptom relief.[19] A related study presented a hypothetical treatment scenario for SAP to individuals in the general community. Participants were randomized to one of three arms that varied by how patients were presented information on PCI and the risk of MI (no information, an explicit statement that PCI does not reduce the risk of my, or an explanation of why PCI does not reduce the risk of MI). Most individuals (71%) in the ‘no information’ arm believed that PCI reduced the risk of MI.[18] A smaller share of patients in the ‘explicit statement’ arm (39%) and ‘explanation’ arm (31%) believed that PCI reduced the risk of MI.[18] Individuals who believed PCI reduced the risk of MI were much more likely to opt for PCI.[18] The results of these studies suggest that individuals have a strong tendency to believe that PCI will reduce the risk of MI and that there may be barriers to information exchange on this topic between physicians and patients. These barriers may be partially overcome by how the information is presented.

1.2.3. Relationship of Health Literacy with Treatment Assignment and Medical Decision-Making

The prior literature on health literacy and treatment assignment is difficult to summarize due to inconsistencies in the studies. Specifically, a scoping review of the literature on health literacy and medical decision-making found that there was little overlap in the type of health literacy measure used (e.g., REALM[37] or TOFHLA[38]), the aspect of medical decision-making being evaluated, and the study populations.[4] The review concluded that general statements about how health literacy relates to medical decision-making was not possible due these limitations.[4]

Several studies have examined the relationship of health literacy with preferences for participation in treatment decisions and the actual levels of participation. Prior research has found that patients with low health literacy were more likely to prefer more passive roles in treatment decisions.[39,40] But other research has found no significant differences in preferences for involvement by health literacy level.[41] In terms of actual involvement, patients with low health literacy have been found to be less likely to ask questions during treatment planning discussions.[41,42] The lower levels of involvement may be explained by patients with low health literacy experiencing greater difficulty understanding the information presented by the clinicians. Patients with low health literacy are more likely to give poor assessments for general clarity and the quality of explanations provided by clinicians.[43] Clinicians were also found to regularly use unclarified jargon terms in a population of low health literacy patients.[44] Therefore, patients with low health literacy may have similar degrees of involvement as other patients if clinicians tailor their explanations to the patient's health literacy level.

Low health literacy has also been linked to a preference for more aggressive care. Several studies have found that patients with low health literacy prefer more aggressive care in the context of end-of-life treatment for dementia.[45-47] These findings may suggest that patients with low health literacy may also prefer more aggressive care (CABG or PCI) for the treatment of (SAP). However, it is unclear how applicable these findings are since the decision for treatment of SAP is very different than the decision for end-of-life care for dementia. We were unable to identify any studies that evaluated the relationship between health literacy and treatment preferences for aggressive care with respect to cardiovascular disease.

1.2.4. Relationship Between Health Literacy and Medication Adherence

The prior literature on the relationship between low health literacy and medication adherence has found mixed results. Three recent systematic reviews have examined this relationship.[3,48,49] Two reviews found inconsistent evidence[3,48] and one that included a meta-analysis found a small, significant association between low health literacy and worse medication adherence.[49] Many of the studies in two of the reviews[3,49] focused on medication adherence for HIV and these results may be less applicable to medication adherence for SAP. One of the systematic reviews focused on medication adherence for cardiovascular disease and diabetes[48] and as such may be more applicable. Of the seven studies included in the systematic review,[50-58] only one study found a significant association between low health literacy and worse medication adherence.[56] Two additional studies found associations between low health literacy and worse adherence that were only significant in unadjusted comparisons.[54,58] Recent studies that were published after this systematic review have continued to provide conflicting evidence: some have found a significant association for health literacy and medication adherence[59,60] while others have not found a significant association.[61,62] Overall, the conflicting findings make it difficult to make a definitive conclusion about the relationship between health literacy and medication adherence. All three systematic reviews concluded that more evidence was necessary to evaluate this relationship.[3,48,49] In particular, research is needed that addresses some of the methodological weaknesses of the existing studies, which include small sample sizes and populations that are difficult to generalize from.[48]

1.3. Significance

SAP is a promising area for research. The high prevalence of the condition (eight million patients in the US[5]) means SAP imposes a large public health burden. Patients with SAP appear to have confusion regarding treatment alternatives. Compelling evidence indicates that patients tend to believe—often mistakenly—that more invasive treatment with PCI reduces the risk of MI and mortality compared to medical therapy.[19,63] Using cardiovascular disease medications as prescribed is strongly associated with better angina-related outcomes. However, medication non-adherence is still a common issue for cardiovascular drugs.[64] Therefore, it is important to understand adherence patterns for these patients.

Health literacy is a key factor that may affect both treatment assignment and medication adherence for SAP patients. Low health literacy may contribute to the confusion surrounding the treatment alternatives for SAP. Previous research suggests that health literacy may act as a barrier for patients making health-related decisions.[39,65,66] However, these studies had small sample sizes and poor generalizability. Low health literacy may also be linked to worse medication adherence. Previous systematic reviews on health literacy and medication adherence found the evidence for such a relationship inconclusive but limited.[3,48,49] The studies included in the reviews typically had small samples and limited generalizability because they are drawn from a single institution or region.[48] Health literacy is an important factor to target since it is potentially modifiable or it can be targeted with interventions. Past research has shown that interventions that are sensitive to health literacy can improve health outcomes and reduce disparities by level of health literacy.[67-71] In contrast, other factors associated with health are either fixed (e.g., age and sex) or are difficult to address with office-based interventions (e.g., socio-economic status).

The proposed research is significant because it overcomes limitations found in past studies and informs potential interventions that are sensitive to health literacy. The analysis uses a 20 percent sample of Medicare claims to generate a larger and more generalizable sample than in previous research. The results provide evidence on how area-based health literacy is related with treatment assignment and medication adherence. The descriptive analysis of the recorded patient-clinician encounters provides additional depth to the analysis. The findings help to inform interventions so they are suitable for patients with limited health literacy skills such as shared decision-making tools[67] and medication reminders.[71]

1.4. Innovation

This dissertation is innovative because it combines Medicare claims data and an area-based measure for health literacy. As noted earlier, samples for prior studies were typically drawn from single or few geographic sites.[40-43,45-47,50-62] Therefore, external validity is a major concern. In addition, the sample sizes for most of these studies was also small (fewer than 500 individuals).[40-43,45-47,50-53,55-62] Such studies were expensive to conduct in part because they required an in-person assessment of health literacy. Medicare data have been used to study medication adherence and treatment assignment outside of the health literacy literature,[72-74] but analyses of health literacy have not included large claims analyses since health literacy measures are typically unavailable with claims data. The area-based measure for health literacy has only recently been developed and validated.[20] The validation study also linked the area-based measure to Medicare claims data to analyze the relationship between community health literacy and 30-day readmissions for patients with acute MI.[20] The area-based health literacy measure has not yet been used to study treatment assignment or medication adherence in a claims database. There are also important limitations to using an area-based measure for health literacy. The limitations include the ecological fallacy and the high correlation between an area-based measure for health literacy and area-based measures for low-income like the ADI.[75] However, using an area-based measure is the only approach that would enable an analysis with a large claims database.

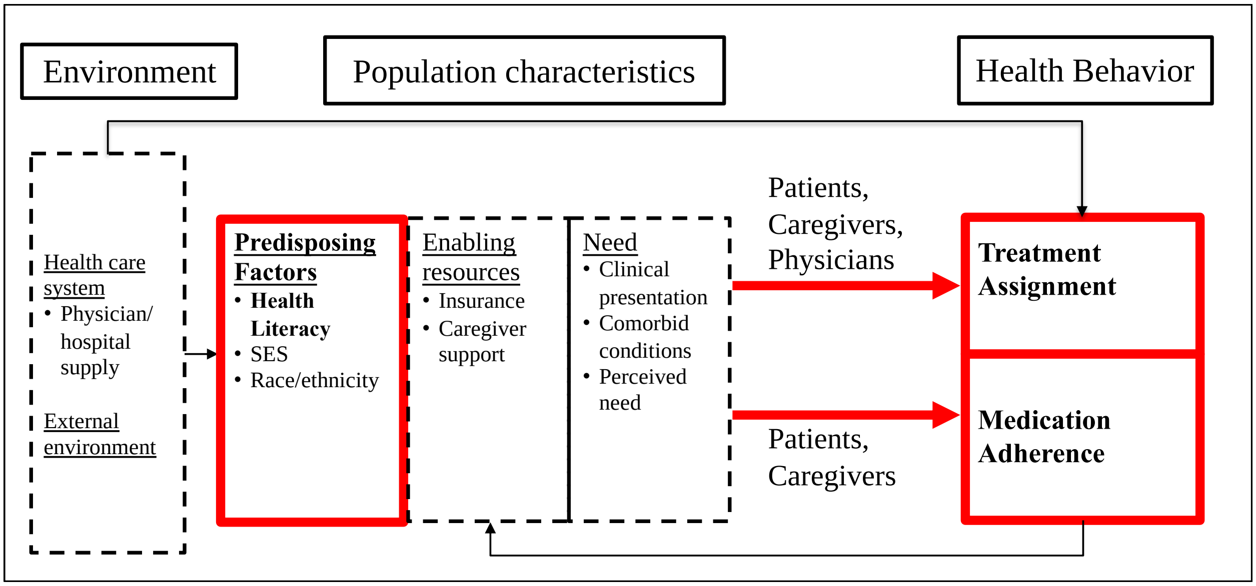
The dissertation research has the advantage of being more nationally representative and less costly than prospective studies. Although the study only focuses on SAP, it demonstrates that the same approach could be applied to other conditions with preference-sensitive treatments or chronic medication use. More generally, this research represents a novel combination an area-based measure with claims data to answer research questions that cannot be answered with claims data alone and for which a prospective study is infeasible due to the sample size and resources required.

1.5. Conceptual Models

1.5.1. Conceptual Model for Aims 1 and 3

The conceptual model for the analyses of the relationship between health literacy and treatment assignment (Aim 1) and health literacy and medication adherence (Aim 3) is a modified version of the Andersen Behavioral Model.[76] This model has been widely used to explain health behavior and utilization of health services in prior research.[77] The model categorizes the major determinants of health behavior as: 1) the environment in which the individual lives, 2) predisposing factors that are inherent individual characteristics, 3) enabling resources which determine individuals' ability to afford and access care, and 4) clinical need. The heavy red lines and arrows in Figure 1.1 identify the key relationships of interest for Aim 1 and Aim 3. The main agents who participate in treatment assignment are patients, caregivers, and physicians. For medication adherence, the main agents are the patients and caregivers. We do not consider physicians to have a large effect on medication adherence since they are unlikely to have much contact with the patient outside of medical visits, though some physicians may be better at encouraging adherence than others.

Figure 1.1. Modified Andersen Conceptual Model of Healthcare Utilization[76]



Note: SES stands for socio-economic status

Environment: The model describes how the environment can interact with patient characteristics to affect health behavior for SAP. The analyses considered physician/hospital supply as key characteristics of the health care system. Prior research suggests that low medical supply in a region is linked to worse outcomes.[78] As such, the analyses controlled for the supply of primary care physicians, cardiologists, and hospital beds per 10,000 residents at the county level. The analyses also controlled for whether a county is rural, since rural areas tend to have lower medical supply than more urban areas.[79] Another key aspect of the external environment is the year in which the beneficiary receives care. Over the period of the study, there were new studies[27] and clinical practice guidelines[6] that may have affected how patients were treated. The year of diagnosis was included in models to account for any changes in clinical practice over time.

Predisposing factors: The analyses focused on the predisposing factor of health literacy as the key independent variable. Specifically, the analyses used an area-based measure of health literacy to assess the relationship between community health literacy with treatment assignment and medication adherence. The methods sections for each analysis describes how the area-based health literacy measure was developed and applied.[17,20] Socio-economic status (SES) is another important predisposing factor that has been found to be significantly associated with health literacy.[17] If SES were not included in the models, then SES would likely be a confounder for health literacy with respect to treatment assignment and medication adherence. As such, the analyses included the area-deprivation index as a control variable for SES.[75] Race and ethnicity may also act as predisposing factors since minority status has been linked to lower quality of care.[80] A control variable for race and ethnicity was also included in the models.

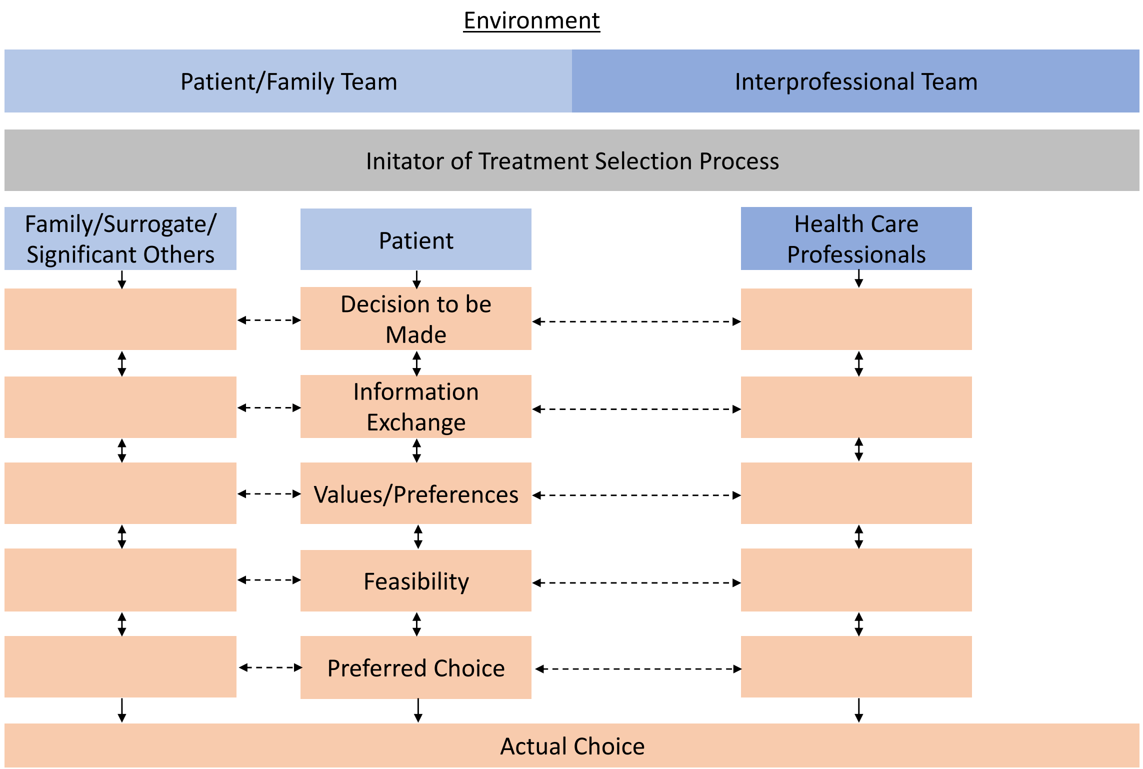
Enabling resources: The main enabling resources are insurance status and caregiver support. For the analyses, all patients had Medicare fee-for-service coverage and there were no uninsured patients. The only differences in insurance status were that some low-income patients qualified as full dual eligible, partial dual eligibles, or recipients of the low-income subsidy for Part D. Full dual eligibles receive cost-sharing reduction and premium support and partial dual-eligibles just receive premium support.[36] Patients who receive the low-income subsidy have lower Part D premiums and lower cost-sharing for medications.[36] The analyses included variables for the proportion of time that a patient was a full dual eligible, partial dual eligible, or received the low-income subsidy. Caregiver support could not be identified in the claims data.

Need: The important clinical aspects that affect care for SAP include the number of arteries that are blocked, which arteries are blocked, the extent of the blockage, anatomic variants, symptom status, age, and important co-morbidites.[6] Many of these characteristics were not available in the claims data. We were able to identify and exclude patients with unstable angina or previous MI. We were also able to identify co-morbidities. We controlled for general co-morbidities by using the Charlson co-morbidity index[81] and separately included an indicator for diabetes, which is associated with treatment outcomes.[10] We also controlled for the age of the patient.

1.5.2. Conceptual Model for Aim 2

The conceptual model for the Aim 2 analysis of recorded patient-clinician encounters for SAP is a modified version of the interprofessional shared-decision-making model.[82] The model was designed to represent shared-decision making between a patient, health care professionals, and family members. Given that average shared decision-making levels are low for many medical decisions,[83] this model may not reflect well what actually occurs for many encounters. Nevertheless, the model is helpful for observing how well actual conversations conform to it. The key elements include the environment in which the medical decision is being made and the family/patient and professional teams working together to make the health decision. The teams work together through five steps that lead to a treatment decision. The two-way arrows between the steps indicate that it is possible to revisit earlier steps at a later point.

Figure 1.2. Modified Version of the Inter-professional Shared Decision-making Model[82]



Environment: The environment in which the discussions take place affects the subsequent steps and the individuals that are involved in the teams. For the Aim 2 analysis, the recording took place at the general cardiology clinic or cardiac catheterization lab at the Mayo Clinic in Rochester, MN. The encounters may have been affected by taking place at the Mayo Clinic, which is a premier health system that may have different approaches to patient-clinician interactions than most health systems. The conversations may have also been affected by whether they took place at the general cardiology clinic or cardiac catheterization lab. Patients seen at the cardiac catheterization lab may be much more likely to receive PCI than patients seen at the general cardiology clinic since the catheterization lab is where PCI is performed.

Teams: The two teams are the patient/family team and the interprofessioanl team. The patient/family team includes the patient, family members, significant others, or other surrogates. In the analysis of recordings, we identified whether the patient had a family member or caregiver present during the encounter. Prior research suggests that family members and caregivers can help support patients with low health literacy.[84] The interprofesional team includes physicians, nurses, and other health providers.

Steps in treatment selection: The five steps for treatment selection inform the outcomes used in the Aim 2 analysis. The quality of information exchange was assessed in three different ways. First, the OPTION12 instrument was used to assess the shared decision-making behavior of the interprofessional team.[85] This outcome measures how the interprofessional team interacts with patient team in the information exchange step. Second, patient understanding of information presented in the information exchange step was assessed using knowledge questions about the treatment alternatives for SAP. Patients completed these questions immediately following the encounter.[63] Third, we assessed the question asking behavior of patients during the encounters. This outcome measured the interaction between the patient and interprofessional team. The values/preferences step was assessed by counting the frequency of patients expressing preferences for treatment during the encounters. The preferred choice step was assessed using the Decisional Conflict Scale (DCS).[86] The DCS measures whether patients feel they have the information needed to express treatment preferences and how uncertain they are. The decision to be made and feasibility steps were not directly assessed, but some of the outcome measures touch upon these aspects of the treatment selection process. More detailed information on the study measures can be found in the Chapter three methods section.

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CHAPTER 2. TREATMENT ASSIGNMENT FOR STABLE ANGINA PECTORIS: THE ROLE OF HEALTH LITERACY

2.1. Overview

Background: Prior research suggests that patients with stable angina pectoris (SAP) have difficulty understanding tradeoffs between treatment alternatives. More invasive treatment has not been associated with better clinical outcomes (e.g., myocardial infarction or death), however, many patients believe that more invasive treatment reduces the risks of these outcomes. Patients living in communities with lower average health literacy may be more likely to have misconceptions and receive more invasive treatment.

Methods: Analysis of fee-for-service (FFS) Medicare beneficiaries (20% random sample). The sample included beneficiaries with an incident diagnosis of SAP in 2007-2013. The treatment alternatives were: 1) medication only, 2) percutaneous coronary intervention (PCI), and 3) coronary artery bypass grafting (CABG) surgery. The key independent variable was an area-based health literacy measure at the census block group level derived from a validated predictive model. This variable was specified as a dichotomous measure (low vs. high). The relationship between treatment and health literacy was evaluated using multinomial logistic regression, controlling for socio-demographic and case mix measures.

Results: The study sample included 15,435 patients. Patients living in communities with low health literacy (n=1,631) were significantly more likely to receive medication only (3.3 percentage points more likely for low vs. high health literacy) and less likely to receive CABG (-3.0 percentage points more likely). The magnitude of the marginal effects decreased after adding an Area Deprivation Index (ADI) to the model to control for area-based socioeconomic status.

Conclusions: Living in communities with lower average health literacy was associated with lower utilization of invasive treatment (PCI or CABG) and higher use of medication only. Treatment assignment may be driven by other factors such as physician assessments or access to care.

2.2. Introduction

About 80 million people, a quarter of all Americans, have poor health literacy.[1] Low health literacy is associated with worse access to care, poorer quality of care, and negative health outcomes for a wide array of conditions.[2] Health literacy may also impact patient's ability to understand treatment alternatives and to participate in treatment decisions.[3] Patient comprehension of treatment options will become even more important as medicine transitions towards patient-centered care and shared decision-making.

The treatment of stable angina pectoris (SAP) is a promising area for evaluating the impact of health literacy on treatment decisions. Treatment depends in part on patient preferences,[4] so patients' ability to understand the tradeoffs between treatment options may influence the care they receive. The most commonly used treatments for SAP are medication only (treatment with prescription medications), percutaneous coronary intervention (PCI) with medication, and coronary artery bypass grafting (CABG) with medication. The alternatives vary in terms of cost, how long it takes to receive symptom relief, and type and risk of complications.

Medication only is the least expensive alternative and has comparable long-term symptom relief relative to PCI in patients with SAP.[4,5] However, a greater share of patients experiences short-term symptom relief from PCI than medication only.[5] PCI is more costly[6] and more invasive than medication only and requires adherence to dual antiplatelet therapy to prevent stent thrombosis.[7] CABG results in more complete symptom reduction than the other alternatives.[8-10] But CABG is also the most invasive (with time needed for surgical recovery),[11] most costly,[12] and has a small risk of death or other serious complications.[13] Outcomes for CABG relative to PCI are similar for patients who have more limited or uncomplicated coronary artery disease. However, for patients with more complex coronary artery disease, there appear to be improvements in major adverse cardiac and cerebrovascular events.[9,14]

The purpose of this analysis was to examine the relationship between health literacy and treatment assignment for SAP among Medicare beneficiaries. Such analyses have historically been difficult to conduct, as measuring literacy skills on an individual-level is logistically difficult and generally involves conducting in-person assessments; this is not plausible for large study samples. Recently, a predictive model of health literacy, which utilizes data from the US census to estimate the average health literacy skills of individuals living in a census block group, was published and validated.[15,16] Such a model allows for investigations of the relationship between health literacy and SAP treatment assignment on an unprecedented level. To assess this potential relationship, the analysis used claims for a 20 percent sample of Medicare beneficiaries. We examined the treatment that patients received (medication only, PCI, or CABG) and evaluated the association with the area-based health literacy measure while controlling for other factors.

2.3. Methods

2.3.1. Data Sources

The main data source was claims for a 20 percent random sample of Medicare for beneficiaries aged 65 and older who had at least one month of simultaneous coverage in fee-for-service Parts A (hospital), B (outpatient medical), and D (prescription drug) insurance from 2007-2014. Parts A and B claims from 2006 were used to exclude patients with SAP prior to 2007 from the sample. The claims data were supplemented with: 1) the Area Health Resource File (AHRF), 2) health literacy estimates at the census block group level,[15,17] and 3) an area deprivation index at the 9-digit ZIP Code level.[18] The AHRF is a database with variables on regional medical supply, socioeconomic status, and health status.[19] This research was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

2.3.2. Sample Selection

Figure 2.1. details the steps in the sample selection process. The steps were designed to select patients with incident diagnoses of SAP on inpatient or outpatient claims who were eligible to receive medication only treatment. Appendix Tables 1-3 provide additional information on the specific codes used in this analysis.

2.3.3. Variable Selection

The dependent variable was a categorical variable for the treatment received: medication only, PCI, and CABG. Patients were categorized as PCI or CABG if they had the treatment within one year of the index date. If patients received both PCI and CABG within the first year, then the patients were assigned based on which treatment occurred first. Patients were categorized as medication only if they had at least one claim for a nitrate and no claims for PCI or CABG within one year of the index date (i.e., date of first claim with a diagnosis of SAP after January 2007).

The key independent variable was health literacy. The analysis used an area-based measure for health literacy. The health literacy measure was estimated using a predictive model developed from the 2003 National Assessment of Adult Literacy (NAAL).[15,16] The predictive model included measures for gender, age, race/ethnicity, education, income, marital status, language spoken at home, rurality, and time in the US.[15] For this study, the demographic measures were derived from the 2010 US Census.[17] The predicted health literacy scores range from 0-500 and are sorted into four NAAL designations: below basic (0-184), basic (185-225), intermediate (226-309), and proficient (310-500). These NAAL designations are based on what skills patients in those categories are able to perform.[1] The use of the predictive model for health literacy has been validated in prior research.[15,17] The variable was operationalized in this study using both a dichotomous measure as well as quartiles based on the national distribution of scores at the census block group level. Previous studies used a dichotomous categorization of “Above Basic” or “Basic/Below Basic” based on NAAL categories to operationalize this variable.[15,17] For clarity, “Above Basic” will be referred to as “high health literacy” and “Basic/Below Basic” will be referred to as “low health literacy.” The quartile specification was also used because it allowed for a more detailed assessment of the pattern of association of health literacy with treatment assignment.

The individual-level variables were limited to the information available in the claims data. The patient-level control variables included race/ethnicity (white, black, hispanic, and other),[20] age, sex, the Deyo version of the Charlson comorbidity index,[21] and indicators for diabetes. Diabetes was included separately from the Charlson comorbidity index because CABG may be more beneficial for patients with diabetes.[22] The analysis also included county-level measures of primary care physicians, cardiologists, and hospital beds per 10,000 residents to control for regional medical supply. Year and state fixed effects controlled for time trends and time-invariant state-specific characteristics.

In our primary analysis, variables for rural status, area deprivation index (ADI),[18,23] and the proportion of patients receiving CABG or PCI from physicians in the service area (defined as the Hospital Referral Region) were excluded because they were expected to be highly correlated with the health literacy variable. The ADI is a neighborhood-level measure for socioeconomic status. The ADI for this analysis was derived from 2000 Census data and it incorporated variables including education, income, employment, and housing.[18,23] The predictive model used to create the health literacy variable also included area-based measures for rurality and income.[15] We included these variables in alternative specifications to assess the robustness of our findings. Rural status was calculated at the county level and was derived from the AHRF. The ADI was merged at the nine-digit ZIP code level. The ADI variable was specified as a dichotomous variable[24] and as quartiles of the ADI based on national data. The dichotomous measure for ADI was used in the models with the dichotomous measure for health literacy and the quartile version of ADI was used in the models with the quartile measure for health literacy.

The proportion of patients receiving CABG or PCI were two area-based time-varying measures at the Hospital Referral Region (HRR) level. These two variables were calculated as three year moving averages to ensure a sufficient number of observations for each HRR and also to allow for changing trends over time. To calculate the proportions, all patients that met the sampling criteria were included except the patient for whom the calculation was made. The reason for this exclusion was so that the proportion receiving PCI or CABG was not affected by the patient's own treatment status. HRR fixed effects to control for time-invariant HRR characteristics were considered but ultimately not included given the large number of HRRs.

2.3.4. Statistical Methods

Multinomial logistic regression models were used to assess the relationship between health literacy and treatment assignment. The dependent variable was a three-category variable: Medication only, PCI, and CABG. The results are presented using the average marginal effects for each variable. The independence of irrelevant alternatives (IIA) assumption was tested using the Hausman-McFadden test[25] to assess the regression coefficients. The results of the test were dependent on which outcome was omitted from the analysis. When medication only was omitted, the test statistic was non-significant ($p=0.95$). However, when PCI was omitted, the test statistic was significant ($p<0.01$). For this analysis, the multinomial logit models were maintained as the main specification.

Five models were estimated for the main analysis. The first model was a bivariate regression of treatment received on health literacy. The second model included the basic controls, excluding area-level variables that were expected to be correlated with health literacy. The third model added both rural status and ADI. The fourth model added the two HRR treatment measures. The fifth model included rural status, ADI, and the two area-based treatment measures. The five models were separately run once using the health literacy dichotomous measure and another time using the health literacy quartiles.

2.3.5. Sensitivity Analysis

To assess the IIA violation, the relationship was re-estimated with treatment collapsed as a two-category variable. The categories were procedures (CABG or PCI) and medication only.

2.4. Results

2.4.1. Descriptive Statistics

Descriptive statistics for the sample of 15,435 beneficiaries are provided by the two-levels of the dichotomous health literacy measure and overall in Table 2.1. Patients living in areas with low health literacy were slightly younger, more likely to be male, and more likely to be a racial or ethnic minority.

Living in areas with low health literacy was also associated with a higher probability of being low-income (full or partial dual eligible or LIS) or being in worse health (diabetes and slightly higher Charlson Comorbidity scores). About half of beneficiaries living in low health literacy areas also lived in areas with high ADI. The correlation coefficient between the health literacy measure and ADI variables was 0.31, which indicates a moderate degree of correlation between these area-based measures. The greatest shares of observations occur in the earliest years. Descriptive statistics stratified by the quartile measure of health literacy are presented in Appendix Table 4. The quartile results were largely consistent with the dichotomous statistics in that living in low health literacy areas tended to be associated with a higher proportion of racial/ethnic minority residents, being in worse health, and having lower median census-tract income.

2.4.2. Regression Results

We focus on regression results for the dichotomous measure of health literacy (Table 2.2.); results for the quartile measure are available in an online appendix. Before adjustment, patients living in the low health literacy areas were more likely to receive medication only (11.9 percentage points) and less likely to receive CABG (-6.1 percentage points) or PCI (-5.8 percentage points) as compared with patients living in high health literacy areas. After adding controls, the effect was reduced for medication only (3.3 percentage points difference between the low and high groups) and CABG (-3.0 percentage points), though both were still statistically significant. Higher deprivation, rural status, dual enrollment in Medicaid, receiving a low-income subsidy, and black race were associated with being more likely to receive medication only and less likely to receive either CABG or PCI. Using the quartile specification of health literacy with adjustment for covariates (Appendix Table 5), medication only and PCI use remained statistically significantly lower among patients living in the lowest health literacy quartile versus the highest quartile, while CABG became non-significant.

Adding ADI, rural status, and treatment area-based measures reduced the magnitude of the marginal effects of the health literacy measure in the dichotomous specification (the last two columns). The decrease in magnitude was much larger when adding rural status and ADI compared to the treatment area-based measures. The marginal effect for CABG by health literacy level remain significant when compared to the highest level for all models. Figures 2.2. (dichotomous) and 2.3. (quartile) show the results in terms of the predicted percentage of patients receiving each treatment alternative in the final model that controls for ADI, rural status, and treatment area-based measures. Figure 2.3 shows that, for the quartile specification, there is a consistent pattern across the quartiles. For example, the first quartile has the highest use of medication only, the fourth quartile has the lowest use of medication only, and the two middle quartiles have levels of use in between the first and fourth quartile.

2.4.3. Sensitivity Analysis

The sensitivity analysis from the logit model for receiving either invasive procedure (PCI or CABG) versus medication only yielded results that were largely consistent with the main specifications (Appendix Tables 8 and 9). Living in a low health literacy area (both dichotomous and quartile specifications) was associated with being less likely to receive either CABG or PCI. After adding ADI and rural status to the models, the dichotomous specification was no longer significant and only the marginal effect for the lowest quartile was still statistically significant.

2.5. Discussion

2.5.1. Summary of Findings

This analysis provided a novel assessment of the relationship between health literacy and treatment assignment for patients with SAP. Patients living in communities with lower average health literacy were more likely to receive medication only. For CABG, the opposite was true: patients living in areas with lower average health literacy were significantly less likely to receive CABG. After adding controls for ADI, rural status, and an area-based measure of patients receiving PCI and CABG, the magnitude of the marginal effects became smaller, but many remained significant. These findings suggest that while some of the association between these variables may be explained other factors such as socioeconomic status, an association between health literacy and treatment received remains even after controlling for other potential explanations, including ADI.

To our knowledge, this study was the first to assess the relationship between health literacy and treatment assignment using claims data and an area-based measure for health literacy. Previous literature examining treatment assignment for SAP showed that patients tended to believe that PCI would reduce the risk of death and myocardial infarction, and that this belief may have influenced the treatment they received.[26,27] Several studies found that patients with low health literacy tend to prefer more aggressive treatment for end-of-life care.[28-30]

Two prior studies analyzed how poor comprehension of the advantages and disadvantages of treatment alternatives affects treatment assignment for SAP.[26,27] The studies found that many patients who received PCI erroneously believed that the procedure would decrease their risk of death or myocardial infarction relative to medication only alone. This finding suggests that current patient-physician interactions are not resulting in patients being informed about the treatment alternatives.[26,27] One possible explanation for continued high rates of invasive treatment (especially PCI) is that patients with low health literacy may find it more difficult to weigh the risks and benefits of treatment alternatives and to make an informed treatment decision.[31,32] Many of the risk factors associated with SAP (advanced age,[33] lower socioeconomic status,[34] and minority status[35]) are also associated with lower health literacy.[15] Another potential explanation is that there are community factors that contribute to misconceptions and higher utilization of PCI. For example, communities with lower average health literacy may be more likely to have misconceptions about treatment spread among neighbors and have fewer resources to correct these misconceptions.

2.5.2. Possible Mechanisms

The average health literacy skills of one's community could potentially affect treatment assignment in several ways. First, patients living in communities with lower average health literacy may have greater difficulty understanding the risks and benefits of treatment options.[26,27] Second, clinicians may discourage patients who they perceive as having low health literacy from receiving PCI because of concerns about these patients not being adherent to dual antiplatelet therapy. Patients who receive PCI must also maintain adherence to dual antiplatelet therapy to avoid complications.[7] Third, patients with low health literacy may have higher distrust of physicians[36] and a result be more reluctant to receive PCI or CABG than patients with high health literacy. Fourth, there may be regional patterns in health care system policies or provider beliefs that affect whether patients receive PCI and CABG and are also correlated with area-based health literacy Fifth, patients living in communities with lower average health literacy may also have worse access to care, which may make it more difficult for these patients to receive CABG or PCI. Prior research has found that patients with low health literacy have worse access to care.[37-39]

In total, the results showed that patients with low health literacy were more likely to receive the non-surgical treatment alternative (medication only) and less likely to receive PCI. The models included controls for other characteristics associated with poor access to care: rural status,[40] variables related to low-income[41] including ADI, full or partial dual eligibility, and the LIS; and racial/ethnic minorities.[42] The marginal effects for health literacy were also in the same direction as these established predictors for poor access. Therefore, it is possible that low area-based health literacy is an independent predictor for worse access to care. Previous research on health literacy and access to care has been inconsistent with some studies suggesting health literacy is a predictor for having worse access to care,[37-39] while others did not.[39,43]

This study provides evidence that low area-based health literacy may act as a barrier to receiving invasive treatment of SAP. However, this barrier may actually benefit patients if PCI is overused. The 2007 COURAGE trial found no significant difference in the risk of death or myocardial infarction for SAP patients without left main coronary artery disease who received medication only compared to PCI and medication only.[44] While the rates of PCI decreased following publication of findings from COURAGE, the decrease was lower than expected.[31,32] The smaller than expected impact may mean that the use of medication only remains lower than would be optimal given the lower cost and risks involved with PCI and CABG. The recent ORBITA trial results also provided evidence that there was not significant improvement in exercise time for patients that received PCI plus medication relative to patients that received a sham procedure plus medication. However, the ORBITA results are controversial because of the small sample size and use of a surrogate outcome (exercise time instead of symptom relief).[45]

2.5.3. Limitations

This analysis has several limitations. First, the analysis uses an area-based measure for health literacy instead of individual assessments. While the area-based measured has been previously validated, individual assessments like the REALM[46] or TOFHLA[47] would have had less measurement error. However, standard assessments are unavailable for the cohort studied. Second, health literacy is highly correlated with socioeconomic status, and the findings may be driven in part by socioeconomic status instead of health literacy. The ADI was included in the analysis as a way to address this concern. But as an area-based measure, the ADI has similar drawbacks when being used as a proxy for individual deprivation. It is unclear whether the effects would have remained had we been able to control for individual socioeconomic status. Third, the analysis used claims data, so many individual characteristics were not observed in addition to health literacy. These individual characteristics that were not measured include: symptom status, disease severity, and anatomic variants. The analysis did include the Charlson Comorbidity index to control for medical comorbidity and an indicator for diabetes status to control for the different treatment guidelines for patients with diabetes.[4] However, these measures do not directly control for the severity of the angina or symptoms the patient is experiencing. Fourth, the study included a random 20% sample of Medicare patients 65 and older with at least one month of simultaneous fee-for-service coverage of Parts A, B, and D. As such, the results may not apply to Medicare beneficiaries younger than 65 or those who never had Part D or fee-for-service coverage. Fifth, multinomial logistic regression models were used as the main specification even though the Hausman-McFadden test for IIA was violated. Violation of this assumption may lead to bias in parameter estimates. Sixth, more observations were observed in earlier years of the analysis. This pattern may indicate that the 'lookback' period was not long enough and that prevalent cases of stable angina were included in the analysis. Alternatively, this finding may be due to how the sample was created. The diagnostic algorithm for identifying patients required multiple diagnoses to be included in the study sample. Patients were assigned to the year in which the first diagnosis took place, which would assign the sample to earlier years than if the year for the second diagnosis were used.

2.5.4. Conclusions

In summary, we found that an area-based measure for low health literacy was associated with a greater use of medication only and less use of PCI and CABG among patients with SAP. Patients living in low health literacy areas may benefit from receiving less invasive treatment given the recent trial results that question the benefit of PCI over medication only.[31,32,45] Future research may yield more insights if individual assessments of health literacy and socioeconomic status become available in survey data sets with sufficient sample size.

2.6. Tables

Table 2.1. Descriptive Statistics by Health Literacy Category

		Low Health Literacy Area (N=1,631)	High Health Literacy Area (N=13,804)	Overall (N=15,435)
Categorical Variables	**Level**	**Freq (Pct)**	**Freq (Pct)**	**Freq (Pct)**
First Treatment Received	Medication only	966 (59.2%)	6,539 (47.4%)	7,505 (48.6%)
	PCI	493 (30.2%)	4,974 (36.0%)	5,467 (35.4%)
	CABG	172 (10.5%)	2,291 (16.6%)	2,463 (16.0%)
Sex	Male	988 (60.6%)	7,235 (52.4%)	8,223 (53.3%)
	Female	643 (39.4%)	6,569 (47.6%)	7,212 (46.7%)
Age	65-70	477 (29.2%)	3,595 (26.0%)	4,072 (26.4%)
	70-75	355 (21.8%)	3,053 (22.1%)	3,408 (22.1%)
	75-80	324 (19.9%)	2,724 (19.7%)	3,048 (19.7%)
	80+	475 (29.1%)	4,432 (32.1%)	4,907 (31.8%)
RTI Race	White	489 (30.0%)	12,417 (90.0%)	12,906 (83.6%)
	Black	644 (39.5%)	539 (3.9%)	1,183 (7.7%)
	Hispanic	403 (24.7%)	406 (2.9%)	809 (5.2%)
	Other	95 (5.8%)	442 (3.2%)	537 (3.5%)
Diabetes	No	737 (45.2%)	7,964 (57.7%)	8,701 (56.4%)
	Yes	894 (54.8%)	5,840 (42.3%)	6,734 (43.6%)
Charlson Comorbidity Index	0	928 (56.9%)	8,885 (64.4%)	9,813 (63.6%)
	1	358 (21.9%)	2,839 (20.6%)	3,197 (20.7%)
	2	193 (11.8%)	1,253 (9.1%)	1,446 (9.4%)
	3	103 (6.3%)	518 (3.8%)	621 (4.0%)
	4+	49 (3.0%)	309 (2.2%)	358 (2.3%)
Year	2007	554 (34.0%)	3,609 (26.1%)	4,163 (27.0%)
	2008	311 (19.1%)	2,516 (18.2%)	2,827 (18.3%)
	2009	205 (12.6%)	1,840 (13.3%)	2,045 (13.2%)
	2010	168 (10.3%)	1,483 (10.7%)	1,651 (10.7%)
	2011	128 (7.8%)	1,322 (9.6%)	1,450 (9.4%)
	2012	119 (7.3%)	1,314 (9.5%)	1,433 (9.3%)
	2013	146 (9.0%)	1,720 (12.5%)	1,866 (12.1%)
Area Deprivation Index Category	Low Deprivation	857 (54.0%)	11,844 (89.4%)	12,701 (85.6%)
	High Deprivation	730 (46.0%)	1,404 (10.6%)	2,134 (14.4%)
Rural Status	Urban	1,362 (83.5%)	10,140 (73.5%)	11,502 (74.5%)
	Rural	269 (16.5%)	3,664 (26.5%)	3,933 (25.5%)
Continuous Variables		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Cardiologists per 10K		0.78 (0.54)	0.66 (0.60)	0.68 (0.59)
PCPs per 10K		6.98 (2.43)	7.16 (2.88)	7.14 (2.83)
Beds per 10K		37.77 (25.65)	33.76 (26.31)	34.18 (26.27)
Full Dual Eligible*		44.4% (48.4%)	15.1% (35.0%)	18.2% (37.8%)
Partial Dual Eligible*		11.3% (30.3%)	5.9% (22.6%)	6.4% (23.6%)
Receives Low Income Subsidy*		63.4% (47.6%)	25.4% (43.2%)	29.4% (45.2%)
Area-Level Measure of Pct. Receiving PCI†		34.1% (9.0%)	35.2% (9.7%)	35.1% (9.6%)
Area-Level Measure of Pct. Receiving CABG†		14.3% (5.5%)	15.0% (5.7%)	14.9% (5.7%)

*Full dual eligible, partial dual eligible, and receives Low Income Subsidy are measured as the percentage of months that beneficiaries meet the criteria in the year following the index date. Note: CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention

†These variables measure the percentage of patients receiving PCI or CABG at the hospital referral region level.

Table 2.2. Marginal Effects for Multinomial Logistic Regression with Dichotomous Specification of Health Literacy Variable

Variables	Bivariate	Basic Controls	Basic Controls, Rural, ADI	Basic Controls, Treatment Patterns	Basic Controls, Rural, ADI, Treatment Patterns
	ME (SE)	ME (SE)	ME (SE)	ME (SE)	ME (SE)
			Medication only		
Low Health Literacy (Basic/Below Basic)	11.86%***	3.33%*	3.36%*	2.94%*	2.90%
	(1.29%)	(1.45%)	(1.51%)	(1.44%)	(1.50%)
Rural			3.43%***		3.09%**
			(1.03%)		(1.03%)
ADI High Deprivation			0.10%		0.17%
			(1.21%)		(1.20%)
HRR PCI & CABG percentages				✓	✓
			PCI		
Low Health Literacy (Basic/Below Basic)	-5.81%***	-0.36%	-1.02%	0.01%	-0.59%
	(1.21%)	(1.49%)	(1.54%)	(1.49%)	(1.54%)
Rural			-1.74%		-1.38%
			(1.04%)		(1.04%)
ADI High Deprivation			1.11%		1.00%
			(1.25%)		(1.24%)
HRR PCI & CABG percentages				✓	✓
			CABG		
Low Health Literacy (Basic/Below Basic)	-6.05%***	-2.98%**	-2.34%*	-2.95%**	-2.31%*
	(0.82%)	(1.11%)	(1.18%)	(1.11%)	(1.18%)
Rural			-1.70%*		-1.71%*
			(0.78%)		(0.78%)
ADI High Deprivation			-1.21%		-1.17%
			(0.95%)		(0.96%)
HRR PCI & CABG percentages				✓	✓
Observations	15,435	15,435	14,835	15,435	14,835

Standard errors in parentheses

*** p<0.001, ** p<0.01, * p<0.05

Note: ADI stands for area deprivation index. CABG stands for coronary artery bypass grafting, HL stands for health literacy, PCI stands for percutaneous coronary intervention.

2.7. Figures

Figure 2.1. Analysis File Flow Diagram.

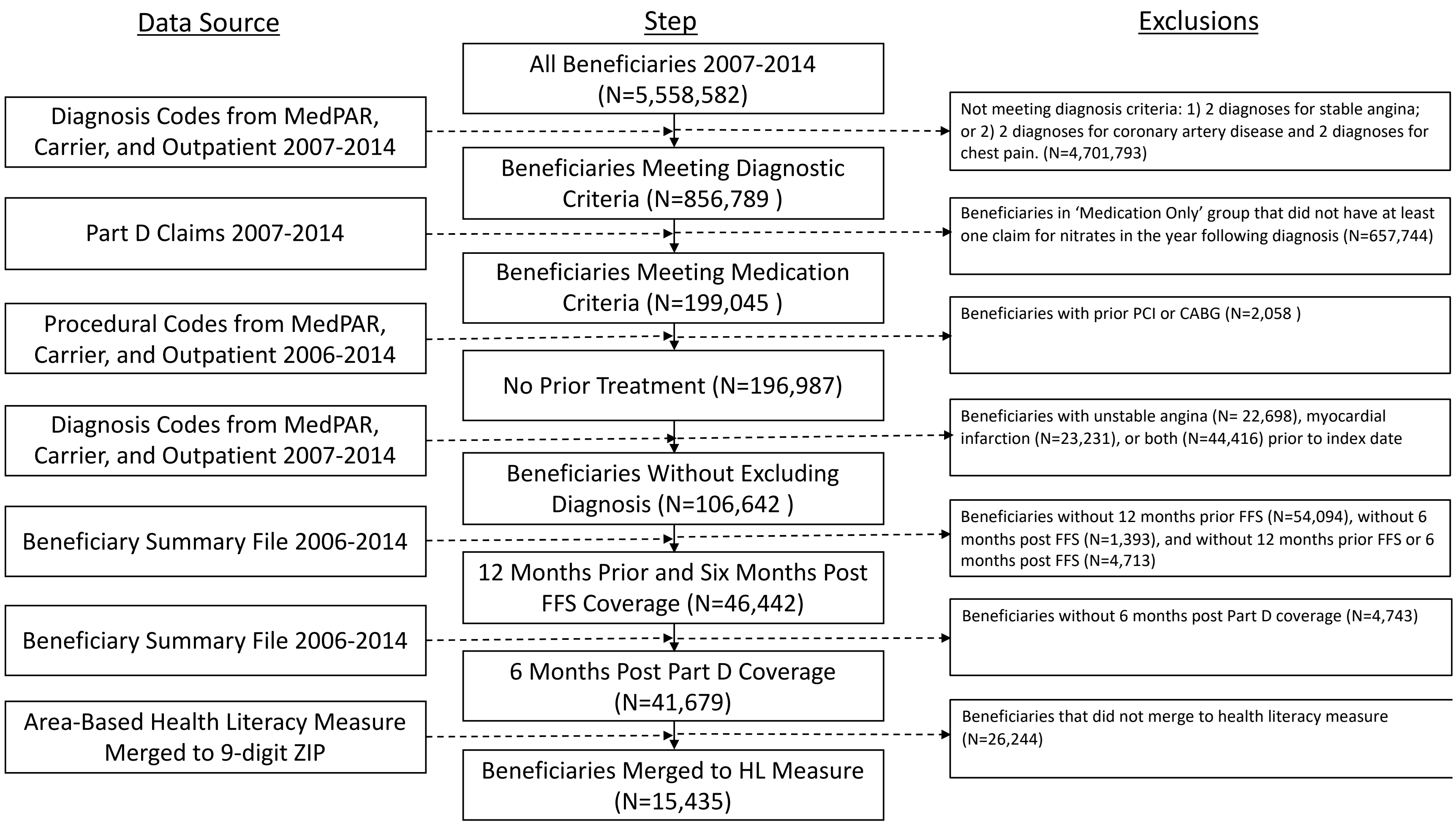


Figure 2.2. Predicted Probabilities of Treatment by Health Literacy Dichotomous Specification with Full Controls

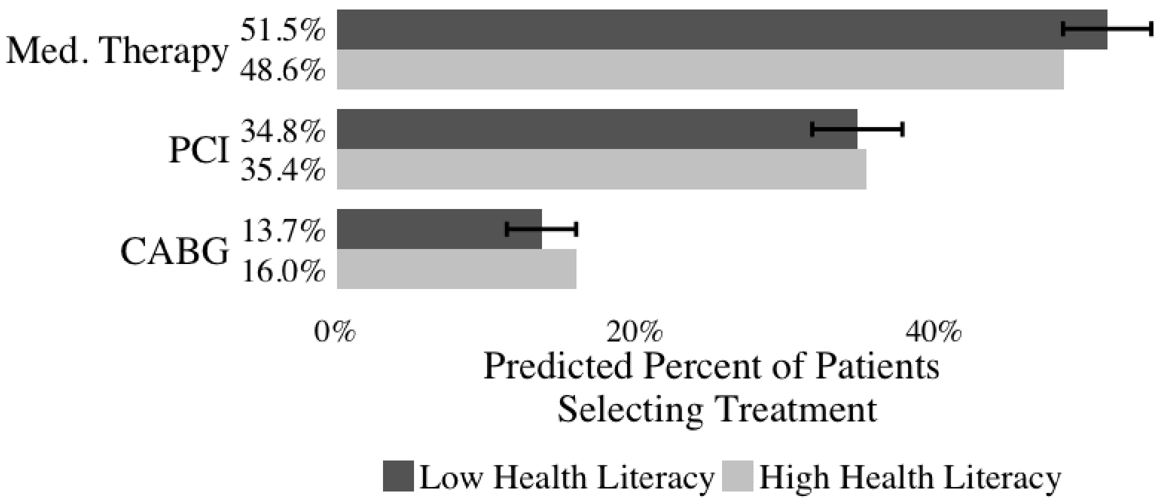
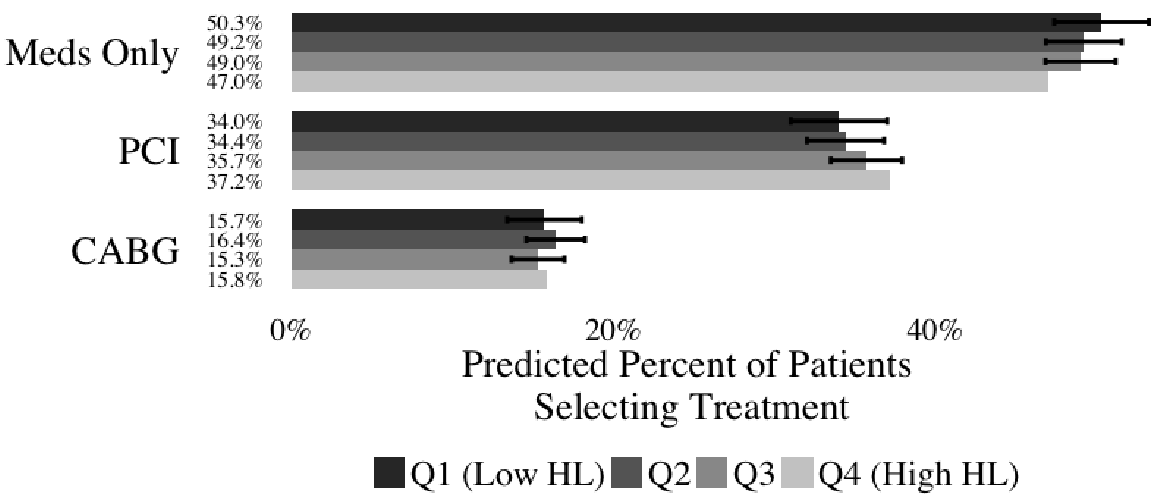


Figure 2.3. Predicted Probabilities of Treatment by Health Literacy Quartile Specification with Full Controls



Note: The predicted probabilities are regression-adjusted. CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention.

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CHAPTER 3. PATIENT-CLINICIAN TREATMENT PLANNING FOR STABLE ANGINA PECTORIS

3.1. Overview

Background: To characterize patient-clinician discussions to decide on treatment strategies for stable angina pectoris (SAP) and to determine whether health literacy affects communication.

Methods: The analysis included a descriptive analysis of patient demographic and questionnaire data from the PCI Choice Trial, a randomized controlled trial that evaluated the impact of a conversation aid for SAP. A qualitative analysis was also conducted on recordings of patient-clinician discussions related to decision making for SAP. The recordings were coded with the OPTION12 instrument for shared decision-making. Two analysts independently assessed the number and types of patient questions and the number and ways patients expressed preferences for treatment.

Results: Patients asked an average of four questions per encounter and only one quarter of questions (53/200) were related to clinical aspects treatment decisions. Clinicians had consistent patterns in their OPTION12 scores. Patients with inadequate health literacy had significantly higher decisional conflict than patients with adequate health literacy.

Conclusions: Patients asked relatively few questions related to the clinical aspects of treatment decision. Clinicians had a large impact on the degree of shared decision-making. Health literacy and clinician communication may act as barriers to communication and could be intervention points to improve communication.

3.2. Introduction

Shared decision making (SDM) for medical decisions has become a prominent goal for the US healthcare system and has been endorsed as the ideal for patient-clinician interaction by the National Academy of Medicine.[1,2] SDM is especially relevant when the ratio of risks to benefits for clinical outcomes are similar and the optimal course of treatment may depend on how patients weigh the risk of complications or side effects, costs of treatment, and the disruption of medication only. Stable angina pectoris (SAP) is a common condition where treatment depends in part on patient preferences in addition to clinical presentation. Patients often misunderstand the risks and benefits of SAP treatment.[3-5] SAP is typically caused by coronary artery disease, a condition that involves arteries leading to the heart being blocked by cholesterol plaque deposits. The arterial blockages reduce blood flow, and with increases in metabolic demand (e.g. exercise) patients may experience chest pain or tightness. The symptoms may restrict patients' abilities to perform day to day activities.

Patients who have SAP have three main treatment alternatives: optimal medication only, percutaneous coronary intervention (PCI), and coronary artery bypass grafting (CABG). The first alternative is medication only. Patients receive anti-anginal medications including long-acting nitrates, beta-blockers, calcium channel blockers, and ranolazine. The second alternative is percutaneous coronary intervention (PCI) plus medications. PCI involves a catheter being inserted into the blocked arteries. The plaque is pushed against the walls of the arteries and a coronary stent is implanted. Additionally, patients need to take the same anti-anginal medications. The third option is coronary artery bypass grafting (CABG) plus medications. Patients receive an invasive procedure (open heart surgery) in which an artery or vein from another part of the body is taken and grafted around the blocked arteries through an opening created in the chest. Patients may also receive the anti-anginal medications.[6] Each alternative has key advantages and disadvantages. Medication only is non-invasive and less expensive. While long-term symptom relief with medication-only is comparable to PCI, PCI may have faster and more complete symptom relief. However, the recent ORBITA trial found no significant difference in exercise time between PCI and a placebo procedure.[7] This finding challenges the idea that PCI produces faster short-term symptom relief than medication only. PCI is more invasive and expensive than medication only, but it is much less invasive and expensive than CABG. CABG has relative fast symptom relief and also generally results in more complete symptom relief than PCI or medication only. However, it is much more invasive and expensive than PCI. Additionally, there is a small risk of death or other serious complications. For these reasons, CABG is less commonly used than PCI for patients with SAP. CABG is typically reserved for patients with more severe blockages or specific co-morbidities such as diabetes for whom the practice guidelines judge the potential benefits to be worth the considerable risks of the procedure.[6]

Notably, the outcomes in terms myocardial infarction and mortality are similar regardless of treatment decision for patients without left main coronary artery disease. The 2007 COURAGE trial, which excluded patients with left main disease, found no significant difference in terms of myocardial infarction or death for patients receiving medication only or PCI plus medication.[8] While a decrease in use of PCI was observed following the trial results, the decrease was lower than expected.[9-11] The relatively small impact may be due to patient confusion about the comparative effectiveness of the alternatives. Patients tend to mistakenly believe that PCI will lower the risk of myocardial infarction or death compared to medication only.[3-5] This confusion may lead to lower use of medication only.

This study examined patient-clinician discussions during treatment decision-making conversations for SAP. The study was a secondary analysis of data from the PCI Choice Trial, which was a randomized controlled trial that evaluated the impact of a conversation aid to facilitate shared decision making for SAP. The PCI Choice Trial found that use of the conversation aid improved patient knowledge about the comparative effectiveness of the treatment alternatives. However, the intervention did not improve the degree of SDM.[12] Follow-up interviews found that clinicians were initially unfamiliar about SDM and uncomfortable changing their practice patterns.[13] In particular, many clinicians used the conversation aid as an education tool rather than as a guide to support the conversation with the patient.[12,13]

The main objective of this study was to use recorded patient-clinician discussions to understand how clinicians and patients communicate about the treatment alternatives. A secondary objective was to examine the potential role that health literacy plays in communication, including how conversations differed between patients with inadequate vs. adequate health literacy. We hypothesized that patients with inadequate health literacy would have greater decisional conflict and less knowledge about the comparative effectiveness of treatment alternatives.

3.3. Methods

3.3.1. Data Source

This analysis used data from the PCI Choice study, a randomized controlled trial to evaluate a conversation aid (PCI Choice) for treatment of SAP.[12,13] The randomized trial enrolled 124 patients who received care at the general cardiology clinic or cardiac catheterization lab at the Mayo Clinic in Rochester, MN. Patients had to be eligible to receive either percutaneous coronary intervention or medication only. About half of the patients received the conversation aid (N=65) and half received usual care (N=59).:

3.3.2. Measures

The PCI trial collected the following data: Patient questionnaires administered before, immediately after, and three months after the treatment selection discussion. The questionnaires assessed demographics, health literacy, patient knowledge, and treatment selection. Video and audio recordings of patient-clinician interactions. The recordings were only collected for a subset of patients (N=54) who consented. Additional details about the trial are available through the study protocol and the results of the trial.[12,13]

Shared decision-making (SDM) was assessed using the OPTION12 Scale, which is a 12-item scale that rates the clinicians' actions to promote SDM. The OPTION12 ranges from 0 (low SDM) to 100 (high SDM). It has been validated[14] and used for a variety of medical conditions including cardiovascular disease.[15] The methods for the collection were described in a previous study.[12] Briefly, the OPTION12 was collected by two independent reviewers and concordance was assessed using the Lin concordance correlation coefficient. The concordance between the two reviewers was found to be high.[12]

Outcome measures were assessed via the patient questionnaire. The first outcome was patient knowledge of angina and the treatment alternatives. The assessment consisted of ten questions asked immediately following the treatment discussion. The questions related to information patients should understand after discussing treatment options with their clinician. These questions were developed for the original study with input from cardiologists who treat patients with SAP.[12] The second outcome was the Decisional Conflict Scale (DCS), which is a 16-item scale used to measure patient perception of uncertainty and effective decision making. The Scale ranges from 0 (low conflict) to 100 (high conflict). The DCS has been validated[16] and applied to cardiovascular disease.[17]

Health literacy was assessed using a validated screening question: “How confident are you filling out healthcare forms by yourself?”[18,19] Patients were defined as having ‘inadequate’ health literacy if they answered “Somewhat,” A little bit,” or “Not at all.”[18,19] Otherwise, patients were classified as having ‘adequate’ health literacy. Previous research has demonstrated that this screening question has good sensitivity and specificity for identifying inadequate health literacy relative to validated instruments including the S-TOFHLA and REALM.[19]

3.3.3. Patient Engagement Measures

Two patient engagement measures were defined for analyzing the recorded encounters. These measures were created for this study to capture information unique to these treatment conversations. The measures of patient engagement were: 1) the number and type of questions patients asked; and 2) the number of times the patient expressed their preferences on treatment. The categories for type of questions appears in the Analytic Approach section. The preferences included stated preferences for any aspect of treatment such as type of therapy and timing of treatment.

3.3.4. Sample Selection

The sample selection process is illustrated in Figure 3.1. The full sample and the recording sample are indicated separately because some measures were only available for the recording sample. The two exclusions were for missing values for the health literacy questionnaire items and limiting to patients who had their encounter recorded. The final samples were 118 for the full sample and 53 for the recording sample.

3.3.5. Statistical Methods

Two reviewers assessed the patient engagement measures and extracted quotes from the recordings. To establish a consistent reviewing process, both reviewers first assessed ten recordings. The interrater reliability was assessed using the intraclass correlation coefficient (ICC).[20] After assessing interrater reliability, discrepancies were discussed and the remaining recordings were divided among the two reviewers.

The patient engagement question types were collapsed into two categories: questions related to clinical aspects of treatment selection and questions related to logistics and clarification. The categories were collapsed to these two categories due to the results of the inter-rater reliability assessment. The first category included questions about: 1) the risk of myocardial infarction or death, 2) the complications or side effects of treatment, and 3) symptom relief. The second category included questions about: 1) logistics and 2) clarification. Logistics questions related to issues such as how long a coronary angiogram would take or whether a follow-up appointment was necessary. Clarification questions related to asking the clinician to explain information that had already been presented, but that the patient did not understand. The ICC was excellent (0.75-1) for the total number of questions asked at each encounter. However, the ICCs were poor (0-0.4) for some of the sub-categories of questions. When the questions were grouped into the larger categories, the ICCs were excellent.

The results were analyzed using descriptive statistics. Key findings were illustrated using quotes from the recordings. The results for the knowledge questions and the DCS were compared for the inadequate and adequate health literacy groups. The mean and distribution were compared and ordinary least-squares regression was used to assess whether there were statistically significant differences by health literacy level controlling for the arm of the study.

The OPTION12 Scale was evaluated at the clinician-level because the items related more to clinician behavior than patient behavior. The analysis of the OPTION12 results was restricted to the three clinicians who treated at least five patients in the study because it would be difficult to establish OPTION12 patterns for clinicians who had fewer than five study patients.

3.3.6. Sensitivity Analysis

An alternative specification for health literacy used two additional questions (Appendix Table 12). The responses for all three questions were added together to form a scale from 0-12 points and patients with six or fewer points were defined as having ‘inadequate’ health literacy.[19] The main specification is recommended because adding the two additional questions does not improve sensitivity or specificity.[19] The purpose of the sensitivity analysis was to assess whether the differences in patient knowledge and decisional conflict by health literacy category were dependent on which health literacy specification was used.

3.4. Results

3.4.1. Descriptive Statistics

Sample characteristics for the full sample and recording sample appear in Table 3.1. A majority of patients in both samples were male. Patients with inadequate health literacy were slightly older and more likely to only have a high school degree or less for educational attainment (73% vs. 20% and 80% vs. 19%). Encounters were longer among patients with inadequate health literacy (19.85 vs. 13.75 minutes in the recording sample). Most patients in the recording sample had a caregiver or family member attend with them (90% vs. 74%).

3.4.2. Patient Questions

Patients asked relatively few questions related to the clinical aspects treatment selection (Figure 3.2.). Most questions either asked about logistics of how the angiogram or PCI would work or clarification about information that was already presented. An example of a question that relates to

> Box A:
> Patient: "Do you feel better after you have a stent typically? Or is it just basically that you don't notice anymore differences? "

treatment selection is shown in Box A. This question asks about how patients experience symptom relief with PCI (stenting), which may affect the decision of whether to receive PCI. On average, patients asked 3.8 questions per encounter and only 24% (0.89 per encounter) of these questions were categorized as relevant to clinical aspects of treatment selection. About half of patients (27/53) asked no questions relevant to the clinical aspects, and a quarter asked only one such question (14/53). Patients who received PCI or CABG tended to ask more questions than patients who received medication only (1.3 vs 0.4) This difference was statistically significant (p=0.012) using a Wilcoxon rank-sum test.

3.4.3. Patient Expressions of Preference

Most patients expressed at least one preference towards treatment (49/53). On average, patients expressed about two preferences per encounter (109 preferences and 53 encounters). Most preferences

> Box B:
> Clinician: "I guess, you know, I will be guided by you. But if you felt that you really can't make a decision, I am happy to suggest."
> Patient: "I was going to say, if you were me, what would you do at this juncture?"

were prompted by the clinician asking the patient for input (75/109). Over a third of patients did not express any preferences that included a rationale (19/53). In these instances, the patients would state their preferences without explaining why they felt that way. In some of these cases, the patients would defer decision-making responsibility to their clinician, as in Box B, where the patient expresses a preference for the clinician to make a treatment recommendation.

3.4.4. Clinician Communication Patterns

In the recordings, the analysts observed that clinicians who had multiple recorded encounters appeared to have consistent approaches used for engaging patients. Some clinicians appeared to have consistent approaches used for engaging patients. One behavior that frequently arose was clinicians that asked patients leading questions, as in Box C.

> Box C:
> Clinician: "So really, it's all about how long you really wanna wait to have your symptoms relieved. Do you want immediate…or do you want…?"
> Patient: "I want immediate."
> Clinician: "All right, that kind of tells me the answer then here."

The clinician appears to be leading the patient to choose the option with faster symptom relief (PCI) by focusing on the advantage of PCI over medication only. Other clinicians made sure to ask questions in a more balanced way, as in Box D.

In Figure 3.3., the OPTION12 scores reflecting low versus high SDM for the three clinicians are consistent with the observations from the recordings. Two of these clinicians (Clinicians 1 and 3) practiced in the cardiac catheterization lab and one (Clinician 2) practiced in the general cardiology clinic). Clinician 1 had consistently low SDM (OPTION12 scores below 25) for 11/12 patients. In contrast, Clinician 2 had consistently high SDM (above) for all 4/8 patients and had no scores below 20. While Clinician 1 and 2 had relatively consistent scores, Clinician 3 had six encounters with low SDM and two with high SDM. Clinician 3 also had a wide range in scores (4 for the lowest and 29 for the highest). However, the relative inconsistency for Clinician 3 may be explained by whether conversation aid was used in the encounter. Clinician 3 had the four lowest SDM scores for all four patients that received usual care and had the four highest SDM for all four patients that received the conversation aid.

> Box D:
> Clinician: "So based on that conversation, what do you think? I'm gonna take pictures today -and if I have a choice between medicines or stenting to make you feel better, which one do you think would be the right choice for you?"

3.4.5. Outcome Measures by Health Literacy Level

Patients with inadequate health literacy were more likely to receive PCI or CABG following the encounter (Table 3.1) than patients with adequate health literacy. Half of patients (11/22) with inadequate health literacy received PCI or CABG while only around a third of patients (31/96) with adequate health literacy received either procedure. However, this difference was found to be statistically insignificant using a Fisher's exact test (p=0.24).

Patients showed a moderate but somewhat varied level of understanding in terms of their performance on the knowledge questions (Figure 3.4.). On average, patients responded correctly to 55% of the questions. Patients performed slightly worse than average for the questions on whether PCI would reduce the risk of myocardial infarction or death relative to medication only (51%) and whether patients who receive medication only have similar symptom relief compared to PCI at one year (46%). The mean and distribution of questions answered correctly were similar for patients by health literacy level (54.2%

for inadequate health literacy and 56.3% for adequate health literacy) and the regression coefficient (Table 3.2) for inadequate health literacy was not statistically significant (p=0.34).

Unlike the knowledge responses, decisional conflict appeared higher among patients with inadequate health literacy (Figure 3.5). The average DCS was greater among patients with inadequate health literacy (23.6 vs. 18.4). Similarly, the percentage of patients with DCS greater than 25 (68% vs. 50%) was also higher in the inadequate health literacy group. A Wilcoxon rank-sum test between health literacy and decisional conflict was statistically significant (p=0.019) and a regression coefficient (Table 3.2.) for inadequate health literacy was not quite statistically significant (p=0.051).

As noted above, the alternative specification for health literacy was used as a sensitivity analysis. The results were mostly consistent, although the rank-sum test became insignificant for DCS (p=0.18). However, the lack of statistical significance is partially due to fewer people being identified as having inadequate health literacy (11 vs. 19).

3.5. Discussion

3.5.1. Summary of Findings

This study provides a novel characterization of patient-clinician discussions using recorded conversations. We found that most patient questions had to do with contextual or clarifying information. Many patients asked no questions related to clinical aspects of the treatments. Patients were only able to answer about half of knowledge questions correctly. This suggests that patients may have not had a clear understanding of the treatment alternatives when expressing their preferences for treatment. We also found that clinicians had consistent patterns in their OPTION12 scores. Among the three clinicians with at least eight encounters, SDM was consistently low or high for the same clinician. This finding suggests that clinicians may have distinct communication styles that are consistent across the patients they treat. Alternatively, this pattern may be explained by the setting in which the encounters took place. The clinician with consistently high scores practiced in the general cardiology clinic whereas the clinicians with consistently low practiced in the cardiac catheterization lab. Patients seen in the cardiac catheterization lab are at a later stage of the treatment process and at this point the decision to receive PCI may have been made. Lastly, we assessed the potential effects of health literacy on knowledge and decisional conflict. Patients with inadequate health literacy had significantly higher decisional conflict than patients with adequate health literacy. Surprisingly, inadequate health literacy was not associated with less knowledge.

To our knowledge, this is the first study to directly characterize patient-clinician interactions among SAP patients. Several previous studies have analyzed patient-clinician discussions for other medical decisions.[21,22] One study analyzed recorded clinician-patient interactions for rectal cancer treatment planning with an approach that was similar to the current study. The authors found that patient values were expressed in fewer than half of the interactions and that patient treatment preferences were expressed in fewer than a quarter of interactions.[21] These findings are consistent with the current study's findings of relatively low patient involvement in treatment planning. While patient preferences were more commonly expressed in this study, the difference was likely due to having less restrictive criteria for what qualified as a preference. Another study conducted a systematic review of OPTION12 scores for a variety of conditions.[15] The mean OPTION12 score in this study (19.5) was similar to the mean score in the systematic review (23).[15] Previous studies have also examined the relationship of health literacy with treatment planning. However, a scoping review of the literature found too many inconsistencies to make conclusions about health literacy and treatment decision-making.[23] More consistent research is needed to understand how the results in this study relate to health literacy and decision making in general.

3.5.2. Limitations

This analysis has several limitations. First, the sample size was small and few patients were categorized as having inadequate health literacy (10/52 for the recording sample, 22/118 for the full sample). Given the small sample size and descriptive nature of the analysis, the findings should be interpreted as exploratory. Second, the analysis did not include racial or ethnic minorities in the recording sample and only one in the full sample. An extensive literature indicates that patient-clinician communication differs when the patients are racial or ethnic minorities.[24,25] Caution is warranted when considering how the results apply to other populations. Third, the analysis took place at the Mayo Clinic, which is a premier health care delivery system. The results may be different for other health systems, especially those that have different cultures or serve different patient populations. Fourth, the OPTION12 score may not fully reflect whether meaningful SDM between patients and clinicians actually occurred. It was observed that in encounters with the conversation aid some clinicians would go through the steps of the aid in a mechanical fashion and still receive relatively high OPTION12 scores. Fifth, the health literacy measure uses a screening question instead of an instrument such as the S-TOFHLA or REALM. While the screening question has been validated against these instruments, it still is less accurate and is based upon patient self-report of their literacy skills instead of a more objective assessment.[18,19] A particular concern is that the response to the screening question may be associated with the DCS since they both relate to confidence. However, a sensitivity analysis that used two additional questions in defining health literacy found largely consistent results.

3.5.3. Conclusions

This analysis provides key insights into what takes place in patient-clinician discussions for SAP in the context of a clinical trial of an SDM intervention. These findings have important implications for understanding how patients and clinicians discuss medical decisions that require important tradeoffs. The results also suggest possible targets for intervention including patients with inadequate health literacy and clinician communication. Future research could confirm the findings for different and larger populations.

The findings from this study suggest potential targets for intervention. We found that patients asked relatively few questions about the clinical aspects of treatment selection and patients with lower health literacy had higher decisional conflict. One potential way to address these issues would be to have more time available, especially for patients with inadequate health literacy. OPTION12 scores tend to be higher when consultations are longer.[15] The additional time may help the patients and clinicians feel less rushed and give the patient more opportunities to ask questions. We also found that particular clinicians seemed to have consistent effects on the degree of SDM in the discussions. A potential explanation is that it was the setting of care that affected the degree of SDM (cardiac catheterization lab vs. general cardiology clinic). One way to address this issue would be move the treatment selection discussion to an earlier stage since the decision may have already been made by the time patients reach the cardiac catheterization lab. An alternative explanation is that clinicians had particular communication patterns that encouraged or discouraged SDM. One intervention to encourage clinicians to involve patients more is a conversation aid, which was the main goal of the PCI Choice conversation aid. However, the results of the trial were somewhat disappointing. While patients in the treatment arm had a significant improvement in knowledge scores, significant improvement did not occur in OPTION12 or DCS scores.[12] Follow-up interviews with clinicians involved in the study found that many of the clinicians were confused about how SDM differs from patient education.[13] This finding is consistent with the observation that many clinicians appeared to be using the conversation aid as an education tool rather than a guide to encourage discussion. Therefore, conversation aids such as PCI Choice may be still be effective when paired with additional training for clinicians.

3.6. Tables

Table 3.1. Descriptive Statistics for Full Sample and Recording Sample by Health Literacy Category

		Full Sample (N=118)		**Recording Sample (N=52)**	
		Adequate Health Literacy (N=96)	**Inadequate Health Literacy (N=22)**	**Adequate Health Literacy (N=43)**	**Inadequate Health Literacy (N=10)**
Variable	**Units**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Age at Visit	Years	68.1 (10.3)	71.5 (11.2)	68.2 (10.3)	73.0 (10.4)
Discussion Length	Seconds			824.7 (482.1)	1191.0 (902.6)
Variable	Value	Freq (Percent)	Freq (Percent)	Freq (Percent)	Freq (Percent)
Patient Gender	Female	28 (29%)	4 (18%)	10 (23%)	2 (20%)
	Male	68 (71%)	18 (82%)	33 (77%)	8 (80%)
Educational Attainment	High school or less	19 (20%)	16 (73%)	8 (19%)	8 (80%)
	Some college or associates degree	38 (41%)	5 (23%)	17 (40%)	2 (20%)
	College graduate or graduate/prof. degree	36 (39%)	1 (5%)	17 (40%)	0 (0%)
Cardiac Procedure Received	PCI	24 (25%)	9 (41%)	16 (37%)	4 (40%)
	CABG	7 (7%)	2 (9%)	2 (5%)	0 (0%)
	Neither PCI nor CABG	65 (68%)	11 (50%)	27 (63%)	6 (60%)
Patient Insurance Status	Private	29 (30%)	7 (33%)	13 (30%)	2 (20%)
	Medicare	47 (49%)	12 (57%)	24 (56%)	8 (80%)
	Medicaid	2 (2%)	2 (10%)	1 (2%)	0 (0%)
	Other	18 (19%)	0 (0%)	5 (12%)	0 (0%)
Caregiver or Family Present	No	NA	NA	11 (26%)	1 (10%)
	Yes	NA	NA	32 (74%)	9 (90%)
Treatment Arm	Usual Care	47 (49%)	8 (36%)	18 (42%)	3 (30%)
	Conversation aide	49 (51%)	14 (64%)	25 (58%)	7 (70%)

Note: SD stands for standard deviation, CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention.

Table 3.2. Regression Output for Knowledge Questions and Decisional Conflict Scale

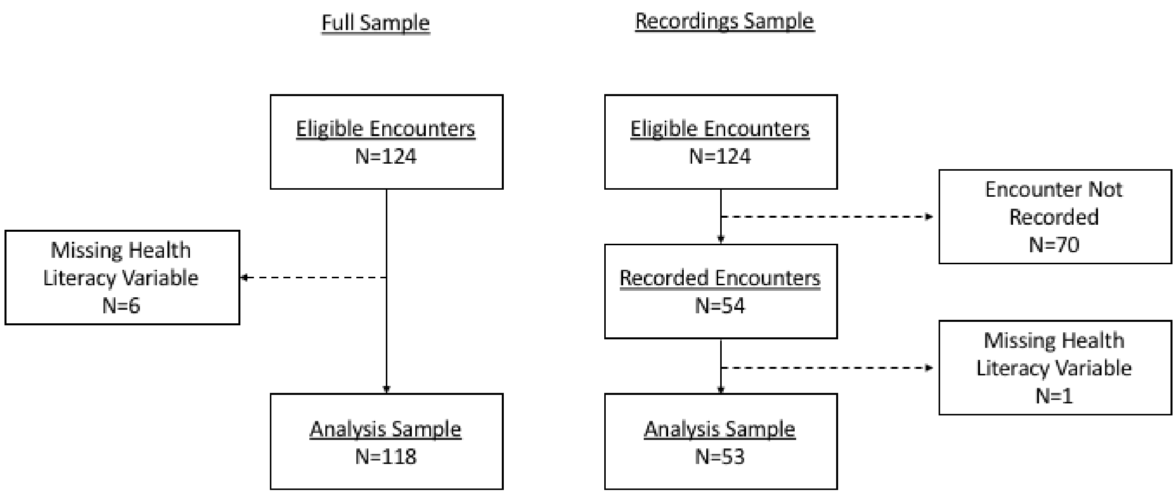
	Knowledge Coefficient (SE)	**Decisional Conflict Coefficient (SE)**
Adequate Health Literacy	-4.72 (4.92)	5.67 (2.88)*
Study Arm—Conversation aid	22.58 (4.48)***	-2.60 (2.76)
Constant	43.54	25.42

***p<0.01, **p<0.05, *p<0.1

Note: SE stands for standard error

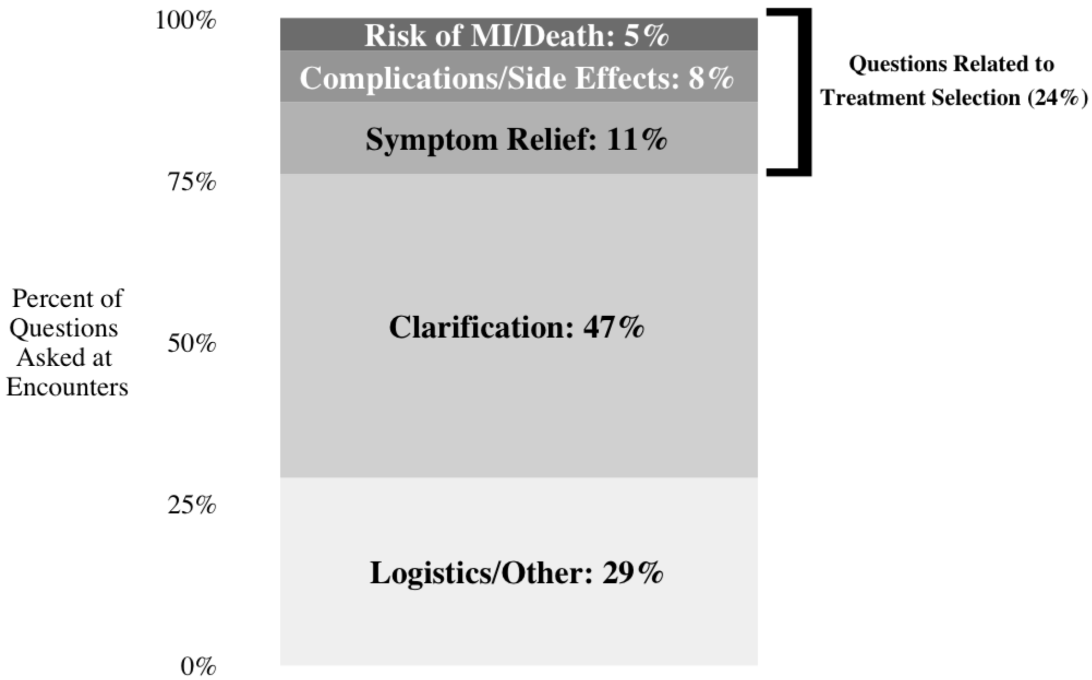
3.7. Figures

Figure 3.1. Sample Flow Diagram



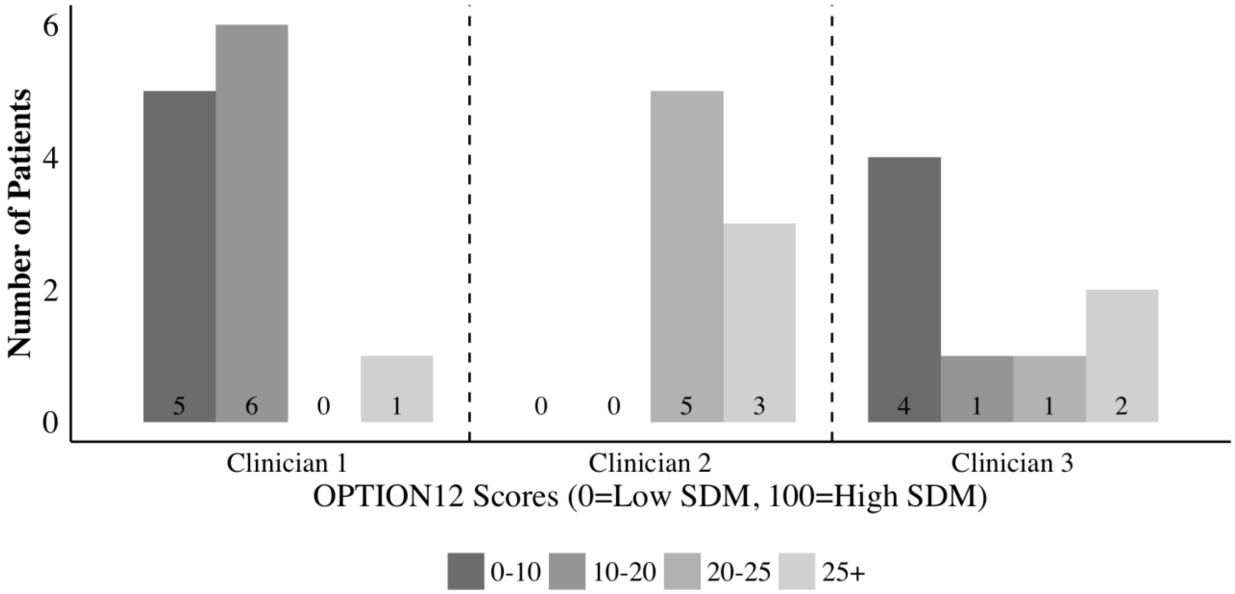
Note: The sample for some analyses is smaller due to missing data on outcome variables.

Figure 3.2. Topics of Patient Questions (N=200) Asked at Encounters (N=53)



Note: 'Clarification' questions included questions that were tied to the logistics of treatment, but not the clinical aspects of decision-making. For example, one question in this category was about how the diagnostic angiogram would work and how long it would take. 'Other' questions related to information that was not directly relevant to the treatment of stable angina pectoris. Some questions included in the 'Other' category were about comorbid conditions or what is occurring in the heart.

Figure 3.3. OPTION12 Scores for Clinicians with 8+ Encounters



Note: Shows OPTION12 Scores for Shared decision-making for the three clinicians in the study with eight or more patient encounters.

Figure 3.4. Distribution of Correct Responses to Knowledge Questions

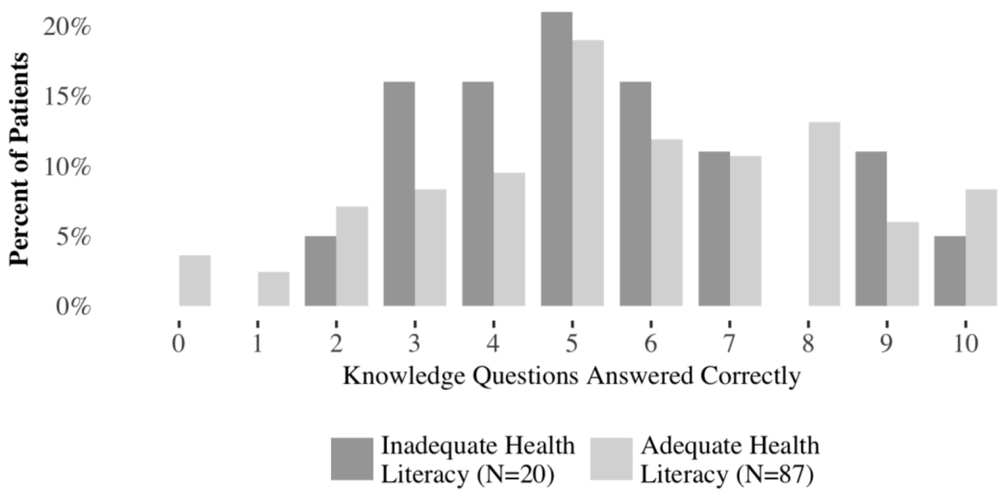
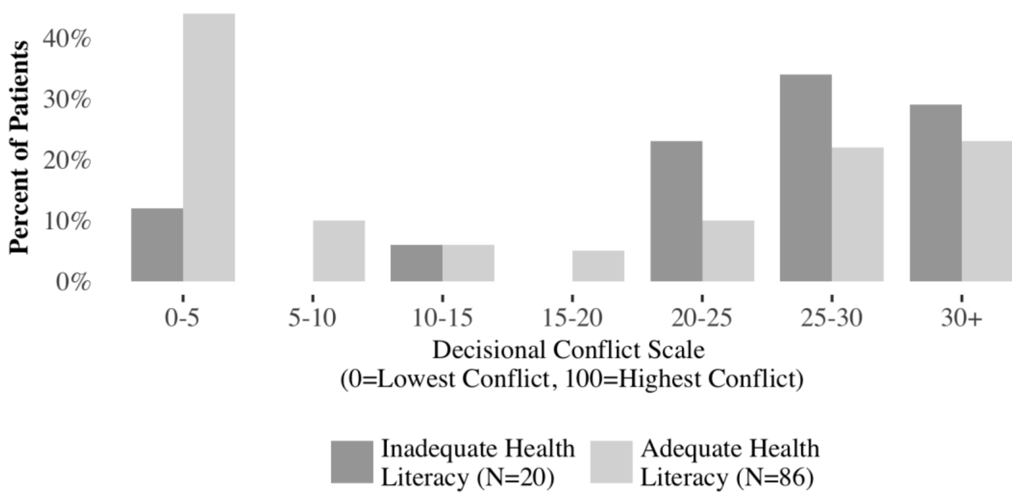


Figure 3.5. Distribution of Decisional Conflict Scale



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CHAPTER 4. MEDICATION ADHERENCE FOR STABLE ANGINA PECTORIS: THE ROLE OF HEALTH LITERACY AND TREATMENT ASSIGNMENT

4.1. Overview

Background: Many patients have low adherence to medications used to treat cardiovascular diseases including stable angina pectoris (SAP). SAP represents a condition where procedures and pharmaceutical only treatments have similar outcomes. Physicians may recommend treatments for patients based on their expectations about patient adherence to medications, and these expectations may be formed by their assessment of patient characteristics such as health literacy. We aim to account for this potential treatment selection and identify the effects of area-based health literacy on medication adherence.

Methods: Observational analysis of Medicare fee-for-service (FFS) beneficiaries (20% random sample). The sample identified beneficiaries with an incident diagnosis of SAP from 2007-2013. The health utilization outcome was a dichotomous measure for whether beneficiaries were adherent to anti-anginal medications over the year following initial diagnosis. Treatment alternatives included: medication only, percutaneous coronary intervention (PCI), or coronary artery bypass grafting (CABG) surgery. Health literacy was constructed as an area-based measure due to lack of an individual measure in claims data. Three different approaches were used to estimate relationships between health literacy and medication adherence while adjusting for treatment selection: 1) probit regression, 2) inverse probability of treatment weighting with probit regression, and 3) two-stage residual inclusion. The instrumental variables used for the last approach were two area-based measures for the proportion of patients receiving CABG and PCI at the hospital referral region (HRR) level.

Results: Mean adherence was 78.7% in the first six months and 67.0% in the second six months. Living in a low health literacy area was significantly associated with a decrease in adherence for the quartile specification of health literacy (marginal effects ranged from -2.6 percentage points to -4.6 percentage points) but not the dichotomous specification. The results were similar in the models that controlled for selection compared to the results in the models that did not control for selection.

Conclusion: Lower health literacy measured at the community level was associated with lower medication adherence, though the differences between the quartile and dichotomous versions meant this finding was not robust. The limited findings do not support the hypothesis that health literacy is an important factor in medication adherence. Further evaluation of health outcomes (rather than just medication adherence) may be fruitful.

4.2. Introduction

Poor adherence to medications is a common problem in the treatment of chronic cardiovascular disease. One study found that among patients with coronary artery disease, only about 46% and 44% of patients reported persistent use of beta-blockers and lipid-lowering medications, respectively.[1] Another study found that among patients with coronary artery disease, two-year adherence to statins was only about 40%.[2] Poor adherence to medications can have important health consequences. For CAD patients, non-adherence to beta-blockers, ACE-inhibitors, and statins was associated with higher mortality, cardiovascular hospitalization, and revascularization.[3] Given the high prevalence of non-adherence and the value of adherence for health outcomes, it is important to understand the predictors of poor adherence. Understanding the factors that predict low adherence may help inform educational and other interventions to promote safe and appropriate medication use.

Low health literacy has been identified as a potential factor affecting adherence.[4] Health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[5,6] Low health literacy is associated with advanced age, lower educational attainment, racial and ethnic minorities, and speaking English as a second language.[7] Patients with low health literacy have reduced skills needed for disease management. In the context of medication use, patients with low health literacy have more difficulty reading and interpreting instructions for taking prescription medications.[8] However, the evidence of a relationship between health literacy and medication adherence is mixed. Two recent systematic reviews found insufficient evidence to make a conclusion about the relationship.[4,9] In contrast, a systematic review conducted a meta-analysis and found that low health literacy was significantly associated with a decrease in medication adherence, but the effect size was small.[10] All three studies emphasized the need for more research.[4,9,10]

In this analysis, we focused on the treatment of patients with stable angina pectoris (SAP). Patients with SAP receive anti-anginal medications including beta-blockers, calcium channel blockers, nitrates, and ranolazine. These medications are taken to relieve the symptoms of angina.[11] In addition to the medications, patients may also receive percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) surgery. PCI involves a catheter being inserted into the blocked arteries. The plaque is pushed against the walls of the arteries, and a coronary stent is implanted to prevent the arteries from becoming blocked again. Coronary artery bypass grafting (CABG) surgery involves open heart surgery in which an artery or vein from another part of the body is taken and grafted around the blocked arteries through an opening in the chest. PCI or CABG patients generally receive the same medications to address symptoms as patients who receive only medications.[11] Patients who receive PCI must also take and remain adherent to dual antiplatelet therapy.[12] Failure of PCI recipients to maintain adherence to dual antiplatelet therapy is associated with an increased risk of stent thrombosis, which is a serious complication that often leads to myocardial infarction and death.[12,13] Patients who receive CABG often experience more complete symptom relief.[14-16] Although CABG is associated with lower risk of major adverse cardiovascular events, it is typically reserved for patients with more complex coronary artery disease than just SAP..[14,17]

Given the limited differences in clinical outcomes between the treatment alternatives, selection by physicians (or joint choice though shared decision making by physicians with patients) into treatment is likely. Treatment selection is certainly based on clinical factors, including clinical presentation of the coronary artery disease and relevant co-morbidities such as diabetes.[11,18] Yet selection may also be based on other factors, such as physician expectations about the ability of patients to remain adherent to medications. Because adherence to dual antiplatelet therapy is so important for preventing complications among patients that receive PCI,[12,13] physicians may attempt to limit this procedure to patients who they believe will be able to maintain high adherence. Physicians may also encourage patients with expected poor medication adherence to receive CABG, since patients with poor medication adherence have better outcomes with CABG.[19] To determine how health literacy is associated with medication adherence it is important to address the possible selection into treatment.

We aimed to identify the relationship of health literacy with medication adherence. First, we assessed the relationship assuming no selection into treatment. Then, the relationship was assessed using inverse propensity of treatment weights (IPTW), where the weights are based only on observed variables. Third, we attempted to address selection based on unobservable variables using an instrumental variable approach (two-stage residual inclusion). The instrumental variables for treatment assignment were area-based measures for the proportion of patients receiving PCI and CABG at the hospital-referral region level. We hypothesized that lower health literacy would be associated with lower medication adherence. We believed that physicians would select patients they expect to be more adherent into PCI due to the need to remain adherent to dual antiplatelet therapy and they would select patients they expect to be less adherent into CABG because the treatment achieves more complete symptom relief even if patients are not adherent to the medications.

4.3. Methods

4.3.1. Data Sources

The primary data source for this analysis was a 20 percent random sample of Medicare claims for beneficiaries aged 65 and older who had at least one month of simultaneous enrollment in fee-for-service Parts A (hospital), B (outpatient medical), and D (prescription drug) between 2007-2013. Claims from 2006 were used to identify and exclude patients who had SAP before 2007. In addition to the claims, the following data source were used: 1) the Area Health Resource File (AHRF),[20] 2) health literacy estimates at the census block group level,[7,21] and 3) an area deprivation index (ADI) at the 9-digit ZIP Code level.[22] The ADI is a neighborhood-level measure for socioeconomic status. The ADI for this analysis was derived from 2000 Census data and it incorporated variables including education, income, employment, and housing.[22,23] The AHRF includes variables on regional medical supply, socioeconomic status, and health status.[20]

The sample selection process appears in Figure 4.1. Briefly, the steps were used to identify patients with incident diagnosis of SAP who were receiving medications to provide symptom relief for SAP. These medications included beta-blockers, calcium channel blockers, long-acting nitrates, and ranolazine.[11] To ensure that the sample included patients who were receiving medications, one sampling criterion was that patients had to have at least one claim for any of these medications in the first six months following diagnosis. While the step helped to ensure the sample had a physician prescribe medication, this step excluded patients with such low adherence that they did not fill any claim for these medications even though a physician may have prescribed them. Information on the procedural and diagnosis codes used to identify the sample appear in Appendix Tables 13-15.

4.3.2. Variable Selection

The dependent variable was a dichotomous indicator for whether the patient was adherent to the medications for SAP over the year following initial diagnosis. Adherence was measured separately over the first six months and the second six months following diagnosis using proportion of days covered (PDC).[24] A patient was considered adherent on a given day if they had an active fill for a prescription to any of the medications for SAP. A patient was considered adherent for the six-month period if they had a PDC of 80% or higher.[25]

Due to lack of an individual measure of health literacy in claims data, health literacy was measured using an area-based variable. The measure was calculated using a predictive model published in the literature that was based upon the 2003 National Assessment of Adult Literacy (NAAL).[7,26] This model included the following demographic characteristics: gender, age, race/ethnicity, education, income, marital status, language spoken at home, rurality, and time living in the US.[7] The demographic measures for this study were derived from the 2010 US census.[21] The model has been validated in prior research.[7,21] The predicted health literacy scores are categorized into four NAAL designations: below basic (0-184), basic (185-225), intermediate (226-309), and proficient (310-500). The designations correspond to particular skills that individuals at those levels are able to perform.[27] In this study, the variable was operationalized in two alternative ways: a dichotomous measure, and quartiles based on the national distribution of values at the census block group level. Previous studies focused on a dichotomous categorization of "Above Basic" or "Basic/Below Basic" based on NAAL categories.[7,21] In this study, "Above Basic" will be referred to as "high health literacy" and "Basic/Below Basic" will be referred to as "low health literacy." The quartile specification was also used since it allows for a more detailed assessment of the pattern of association of health literacy with medication adherence.

Treatment was a categorical variable for the initial treatment the patients received: medication only, PCI, or CABG. Patients were assigned as PCI or CABG if they had the procedure within a one year following the index date of initial diagnosis. For patients who received both PCI and CABG, the patient would be assigned to the treatment they received first. Patients who did not receive PCI or CABG within the first year were assigned to medication only.

The study also included the following control variables: race/ethnicity (white, black, hispanic, and other),[28] sex, age, the Deyo version of the Charlson comorbidity index,[29] and an indicator for whether the patient had diabetes. Diabetes was measured separately because the comparative effectiveness of treatment alternatives for SAP varies for patients with diabetes.[18] Diabetes was excluded from the Charlson comorbidity index to avoid double-counting. In addition to the individual-level variables, the analysis also included county-level measures of primary care physicians, cardiologists, and hospital beds per 10,000 residents to account for differences in regional medical supply. Year fixed effects were included to control for time trends.

In the main analysis, rural status and the Area Deprivation Index (ADI)[22,23] were not included because the predictive model used to create the health literacy measure included area-based variables for rurality and income.[7] We expected these variables to be highly correlated with the health literacy measure, so they were added in additional specifications of the models. Rural status came from the AHRF and was determined at the county-level. The ADI was also specified as a dichotomous variable[30] and as quartiles based on the national distribution. The dichotomous ADI version was used in the specifications that used the dichotomous health literacy measure, and the quartile ADI version was used in the specifications that used the quartile health literacy measure.

4.3.3. Statistical Methods

The first estimation approach was a probit regression that included treatment and area-based health literacy as the key explanatory variables. The results are presented in terms of average marginal effects and the standard errors were clustered at the patient level to account for multiple observations (the first and second six month periods).

The second approach was a probit regression that included inverse probability of treatment weighting (IPTW) to adjust for treatment selection based on observed variables. Propensity score analysis has been most commonly applied to analyses that include two treatment levels.[31,32] Propensity score analysis can be extended to three or more treatment groups by using the generalized propensity score.[33] The generalized propensity score ($P(T_i=t|X)$) is defined as the probability that the patient receives the treatment they were assigned ($T_i=t$) to conditional on observed covariates (X). The weights (w_i) for IPTW with multiple treatments are defined as one divided by the generalized propensity score:[33]

$$w_i = \frac{1}{P(T_i = t|X)}$$

In this analysis, the propensity scores were calculated using generalized boosted modeling (GBM).[34,35] Briefly, GBM is an iterative approach that uses regression trees to identify improvements to the model after each iteration. A key advantage of GBM is that interactions and higher order terms are automatically generated. In addition, GBM often performs better than approaches such as logistic regression where the analyst needs to specify the functional form directly.[34,35]

GBM was implemented in 'R' using the package 'twang.' The standardized mean differences for the unweighted and weighted samples for one of the specifications appears in Appendix Table 16. The standardized mean difference was used to evaluate the success of the weighting. Generally, a cutoff of 0.1 has been used to assess standardized mean differences.[31,32] Before weighting, the standardized mean differences were 0.1 or greater for 15/75 comparisons. After weighting, only 4/75 comparisons had values of 0.1 or greater. In addition, Figures 4.2., 4.3, and 4.4 show the density plot for the propensity scores by each treatment alternative. The plots show a large degree of overlap, which suggests sufficient common support. After calculating the weights, they were incorporated into the probit regressions as sampling weights. The regressions included the same control variables that were used to create the propensity scores. Including the control variables after applying IPTW controlled for residual confounding[36-38] and made the model 'doubly-robust.'[36] The standard errors were clustered at the patient level to account for multiple observations (the first and second six month periods).

The third approach was instrumental variable (IV) analysis using two-stage residual inclusion (2SRI).[39] Unlike the two previous approaches, this approach directly attempted to model the selection into treatment. 2SRI involves a first-stage model in which the endogenous treatment variable (PCI, CABG or medication only) is the dependent variable, which is regressed on the instrumental variable(s) and the exogenous regressors. The residuals from the first stage are calculated and then included in the second stage regression in addition to the endogenous regressor.[39] 2SRI is consistent when used for non-linear models, whereas two-stage predictor substitution (i.e., the equivalent of two-stage least squares for non-linear models) is not a consistent estimator.[39] In this analysis, the first stage was a multinomial logistic regression model because the endogenous variable was the three-category treatment assignment (medication only, PCI, or CABG). Medication only was used as the reference category, and the residuals were calculated as one minus the predicted probability of receiving the treatment if the patient received that treatment and zero minus the predicted probability of receiving the treatment if the individual received a different treatment. The residuals were calculated separately for PCI and CABG and then the raw residuals included in the second stage probit regression in addition to the categorical treatment variable. To obtain accurate standard errors that accounted for the first stage regression, we computed the standard errors using 500 bootstrap replications.

The instrumental variables used in this analysis were two area-based, time-varying measures that were calculated at the Hospital Referral Region (HRR) level. In previous research, physician treatment patterns have been used as IVs.[40] In this analysis, the treatment patterns were calculated at a regional level because patients may have had claims with different physicians based on the treatment they were assigned to, so it would not have been possible to examine treatment patterns at the physician level. The measures were calculated as three year moving averages, which ensured that a sufficient number of observations were available for each HRR and to allow changes in treatment patterns over time. To calculate the measures, all patients were included except for the patient for whom the calculation was being made. The reason for excluding the patient was so that the proportion of patients receiving PCI or CABG was not changed by the patient's own treatment status.

IV analysis makes three assumptions.[41] The first assumption is that the IVs must be strongly related to the endogenous regressors. The use of instruments that are only weakly associated with the endogenous variables can lead to biased results.[42] This assumption is often tested using an F-statistic of the IVs in the first stage.[43] In this analysis, the first-stage was a multinomial logistic regression model, so a chi-square test was used to test whether all the coefficients for the IVs were equal to zero. In all specifications, the null was strongly rejected ($p<0.001$). The next assumption (endogeneity) is that the endogenous regressor is actually endogenous. This assumption is often tested by including both the residuals from the first stage in addition to the endogenous regressor and assessing the statistical significance of coefficients on the residual terms.[44] However, this test is only applicable to linear models. The assumption can still be assessed by comparing the marginal effects from the 2SRI model with the marginal effects from the first approach that ignores selection. The last assumption (exclusion restriction) is that the IVs do not belong in the second stage regression.[45] This assumption cannot be tested directly when the system is exactly identified (i.e., the number of endogenous regressors equals the number of instrumental variables). Instead, the assumption must be justified using theory.[46] In this case, we argue that regional patterns in treatment assignment would be unrelated to an individual's medication adherence except through the treatment patients actually receive. Medication adherence is an individual behavior, and potential area-based predictors for its use are already being controlled for (health literacy, ADI, rurality, and regional medical supply). Therefore, we expect the geographic variation in treatment assignment to meet the exclusion restriction. In the limitations section, we note a potential violation of the exclusion restriction that we were unable to address in the model.

4.3.4. Sensitivity Analyses

Sensitivity analyses were performed to assess the possibility of interaction effects between health literacy and the treatment to which patients were assigned. The interactions could not be included directly because the IV specification was exactly identified, and adding additional interaction terms with the endogenous variable (treatment assignment) would have made the model under-identified. Instead, the relationship was assessed by conducting stratified analyses that limited the analysis to subsets of the data. The analyses were run separately for the lowest health literacy quartile and the highest health literacy quartile.

4.4. Results

4.4.1. Sample Characteristics

Table 4.1. shows descriptive statistics for the 17,516 patients included in the sample broken out by treatment alternative. About two-thirds of the sample were assigned to medication only. Only 22 percent received PCI and 10 percent received CABG. The percentage of patients that were adherent (PDC > 80%) ranged from 75 to 80 percent in the first six-month period and from 63 to 68 percent in the second six-month period. Patients who received medication only were more likely to be living in a low health literacy area, male, a racial/ethnic minority, and older. Descriptive statistics stratified by health literacy level appear in Appendix Table 17. The health literacy measure and ADI measure were moderately correlated ($\rho = 0.315$).

4.4.2. Approach One: Probit Regression

The results for the first approach that used the dichotomous health literacy variable appear in Table 4.2. In the first specification without ADI and rural status (column M1), living in a low health literacy area relative to a high health literacy area was associated with a decrease in the percentage of adherent patients (-2.1 percentage points). This marginal effect was not statistically significant (p=0.07). Adding ADI and rural status slightly attenuated the marginal effect for health literacy (Column M2). For the quartile specifications (Appendix Table 18), living in the lowest health literacy quartile relative to the highest quartile was associated with a significant decrease (-2.6 percentage points); the magnitude increased to -3.1 percentage points after adding ADI and rural status. The marginal effects for all other quartiles relative to highest quartile were not statistically significant. The marginal effects for PCI and CABG were negative and generally consistent across all specifications.

4.4.3. Approach Two: Probit Regression with IPTW

The results for second approach (Table 4.2., columns M3 and M4) were largely consistent with the first approach. The magnitude of the marginal effect on adherence for living in a low health literacy area was similar (-2.1 percentage points in the specification without rural and ADI), although this result was not statistically significant due to larger standard errors. The results were also consistent in the models that used the health literacy quartiles (Appendix Table 18). The marginal effects for the lowest health literacy quartile relative to the highest quartile increased in magnitude (to -3.2 percentage points from -2.6 percentage points). The marginal effects for PCI and CABG were similar to the first approach in magnitude and direction.

4.4.4. Approach Three: 2SRI

The results for the third approach (Table 4.2., columns M5 and M6) were similar for health literacy. Living in a low health literacy area was associated with a decrease in adherence (-1.4 percentage points for the model that did not control for ADI and rural status). This marginal effect was in the same direction as in the models that did not control for selection, but the marginal effect was smaller in magnitude and remained non-statistically significant. In the quartile specification for health literacy (Appendix Table 18), the marginal effect for the lowest quartile relative to the highest quartile was also smaller, but remained statistically significant. Figure 4.4 illustrates the relative consistency for the health literacy marginal effects across the different estimation methods and specifications. The marginal effect for receiving PCI and CABG differed considerably compared to the first two estimation methods. The marginal effect for receiving PCI was in the same direction as in the models that did not control for selection, but the magnitude was larger. The marginal effects for CABG shifted from negative to positive and very large in magnitude. The standard errors also increased considerably for PCI and CABG, which is often the case for IV analysis.

4.4.5. Sensitivity Analysis

The results from the sensitivity analysis that assessed possible interactions between health literacy and treatment assignment appear in Table 4.3. The standard errors were large because the estimation method was 2SRI and the sample size was smaller. The marginal effects for CABG relative to medication only were similar for the lowest (19.2 percentage points) and highest (15.8 percentage points) quartiles. The marginal effects for PCI were more dissimilar. The marginal effect for the lowest quartile was -10.4 percentage points compared to -2.7 percentage points for the highest quartile. However, this difference was not statistically significant due to the large standard errors. The results of the sensitivity analysis support a potential interaction effect between health literacy and receiving PCI.

4.5. Discussion

4.5.1. Summary

This study provided a thorough analysis of health literacy as a predictor for poor medication adherence using advanced methods to account for potential selection into treatment. When considering a dichotomous area-based health literacy measure, living in communities with low health literacy was not statistically significantly associated with adherence. The estimated marginal effect decreased in magnitude after including additional controls for area characteristics that may be related to literacy (i.e., ADI and rural status) or when alternative estimation methods were used. In the quartile specification for health literacy, living in areas of the lowest quartile relative to the highest quartile was associated with a significant decrease in adherence and this result was robust to additional controls and estimation methods. The marginal effects for PCI and CABG differed in the models that controlled for selection compared to the models that did not control for selection. These findings support the hypothesis that there was selection into treatment. The marginal effects for health literacy were not sensitive to whether the model controlled for selection into treatment. The results provided limited evidence that area-based health literacy was a predictor for poor adherence.

4.5.2. Possible Mechanisms and Implications

To our knowledge, this analysis is among one of the first to assess the relationship of health literacy and medication adherence using a large claims database and an area-based measure for health literacy. Prior systematic reviews examining the relationship between health literacy and medication adherence have either found inconsistent evidence[4,9] or a small effect.[10] The findings in the analysis provided only limited evidence for a relationship between area-based health literacy and medication adherence.

It is unclear whether the area-based health literacy measure would be helpful for informing interventions to improve medication adherence. Previous research has documented successful interventions to improve adherence for cardiovascular-related diseases including informational mailings,[47] telephone follow-up,[48] and pharmacist-led interventions.[49] Given the limited nature of the findings presented in the current study and the small magnitude of the marginal effects, area-based health literacy does not appear to be a strong predictor for medication adherence for patients with SAP. More research is necessary to design interventions that promote safe medication use among patients with low or high health literacy skills.

4.5.3. Limitations

This analysis had several important limitations. First, claims data enable a large sample size but do not allow calculation of an individual measure of health literacy. The area-based measure has been validated in prior research,[7,21] but individual assessments such as the REALM[50] or TOFLHA[8] would probably have estimated individual health literacy with less error. Second, low health literacy is associated with low socioeconomic status. As such, the results may be explained by low socioeconomic status instead of low health literacy. We included the ADI to see the effect of also controlling for area-based socioeconomic status; high correlation between ADI and area-based health literacy may have resulted in the lack of statistically significant differences in adherence in relation to low versus high area health literacy. The claims data also precluded use of an individual measure of socioeconomic status. Third, there have recently been concerns about 2SRI producing biased results.[51] Because of this concern, we did not focus on interpreting the marginal effects for PCI and CABG, which varied widely when using the 2SRI estimation method. Fourth, we had to make the assumption that the IVs met the exclusion restriction. While we believe that the regional treatment patterns were not associated with individual medication adherence except through being more likely to receive CABG or PCI, we could not directly assess this assumption. The assumption could be violated if regional treatment patterns were associated with efforts to encourage adherence in those regions. For example, regions that have higher utilization of medication only may be better at promoting medication adherence among their patients. Evidence supports such regional specialization in the treatment for myocardial infarctions.[52] Fifth, we were unable to directly observe symptoms or angina severity using the claims. We did control for co-morbidities using the Deyo Charlson co-morbidity index as well as diabetes status since diabetes affects the treatment for SAP.[53] Sixth, we were only able to observe medication claims and were unable to determine if patients were actually taking the medications. It is possible that actual adherence would be lower if we were able to observe whether patients actually consumed all pills for which they had claims. Seventh, the adherence measure included medication use on days before patients received PCI or CABG. The reason for this issue was that the period over which adherence was measured started at the date of first diagnosis. The start date of the adherence period could not have been the date of the first procedure since there would be no relevant date for patients that received medication only. In contrast, patients were categorized to PCI or CABG based on whether they received the procedure at any point during the follow-up period. Most patients received (about 70%) the procedure within the first 60 days following diagnosis, so most of the days occurred after the procedure. However, it is possible the results would be different if the analysis only included days following the procedure.

4.5.4. Conclusions

In summary, we found limited evidence for a small relationship between living in low health literacy communities and low medication adherence. We also found evidence for selection into treatment. Future research using individual assessments of health literacy and measures of symptoms and angina severity could be insightful if such information becomes available in a survey with sufficient sample size. Future research could also extend this analysis to evaluate health outcomes for these patients following treatment assignment.

4.6. Tables

Table 4.1. Descriptive Statistics by Treatment Category

Categorical Variables	Level	Medication Only (N=11,902)	PCI (N=3,924)	CABG (N=1,690)
Adherent (PDC>80%) First Six Months Following Diagnosis	Adherent	9,457 (79.5%)	3,069 (78.2%)	1,262 (74.7%)
	Non-Adherent	2,445 (20.5%)	855 (21.8%)	428 (25.3%)
Adherent (PDC>80%) Second Six Months Following Diagnosis	Adherent	8,126 (68.3%)	2,547 (64.9%)	1,058 (62.6%)
	Non-Adherent	3,776 (31.7%)	1,377 (35.1%)	632 (37.4%)
Health Literacy	Low Health Literacy Area	10,474 (88.0%)	3,573 (91.1%)	1,579 (93.4%)
	High Health Literacy Area	1,428 (12.0%)	351 (8.9%)	111 (6.6%)
Sex	Male	7,658 (64.3%)	1,824 (46.5%)	543 (32.1%)
	Female	4,244 (35.7%)	2,100 (53.5%)	1,147 (67.9%)
Age	65-70	2,878 (24.2%)	1,231 (31.4%)	530 (31.4%)
	70-75	2,273 (19.1%)	1,076 (27.4%)	506 (29.9%)
	75-80	2,198 (18.5%)	805 (20.5%)	355 (21.0%)
	80+	4,553 (38.3%)	812 (20.7%)	299 (17.7%)
RTI Race	White	9,665 (81.2%)	3,384 (86.2%)	1,470 (87.0%)
	Black	1,094 (9.2%)	227 (5.8%)	59 (3.5%)
	Hispanic	657 (5.5%)	202 (5.1%)	96 (5.7%)
	Other	486 (4.1%)	111 (2.8%)	65 (3.8%)
Diabetes	No	7,389 (62.1%)	2,135 (54.4%)	858 (50.8%)
	Yes	4,513 (37.9%)	1,789 (45.6%)	832 (49.2%)
Charlson Comorbidity Index	0	7,618 (64.0%)	2,660 (67.8%)	1,140 (67.5%)
	1	2,386 (20.0%)	768 (19.6%)	321 (19.0%)
	2	1,095 (9.2%)	334 (8.5%)	159 (9.4%)
	3	507 (4.3%)	109 (2.8%)	52 (3.1%)
	4+	296 (2.5%)	53 (1.4%)	18 (1.1%)
Year	2007	3,384 (28.4%)	909 (23.2%)	410 (24.3%)
	2008	2,140 (18.0%)	718 (18.3%)	305 (18.0%)
	2009	1,463 (12.3%)	578 (14.7%)	245 (14.5%)
	2010	1,132 (9.5%)	470 (12.0%)	201 (11.9%)
	2011	1,073 (9.0%)	409 (10.4%)	181 (10.7%)
	2012	1,104 (9.3%)	364 (9.3%)	161 (9.5%)
	2013	1,606 (13.5%)	476 (12.1%)	187 (11.1%)
Area Deprivation Index Category	Low Deprivation	10,179 (85.5%)	3,379 (86.1%)	1,490 (88.2%)
	High Deprivation	1,723 (14.5%)	545 (13.9%)	200 (11.8%)
Rural Status	Urban	8,986 (75.5%)	2,939 (74.9%)	1,273 (75.3%)
	Rural	2,916 (24.5%)	985 (25.1%)	417 (24.7%)
Continuous Variables		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Cardiologists per 10K		0.68 (0.60)	0.68 (0.61)	0.66 (0.55)
PCPs per 10K		7.23 (2.88)	7.13 (2.86)	7.10 (2.72)
Beds per 10K		34.12 (27.03)	34.08 (24.60)	33.18 (29.57)
Full Dual Eligible*		22.4% (40.8%)	11.1% (30.7%)	9.2% (28.1%)
Partial Dual Eligible*		6.9% (24.4%)	5.4% (21.7%)	4.8% (20.4%)
Receives Low Income Subsidy*		34.5% (47.1%)	21.0% (40.5%)	18.3% (38.3%)
Area-Level Measure of Pct. Receiving PCI		21.6% (7.0%)	23.3% (7.2%)	22.5% (6.9%)
Area-Level Measure of Pct. Receiving CABG		9.2% (4.3%)	9.4% (4.3%)	9.8% (4.2%)

*Full dual eligible, partial dual eligible, and receives Low Income Subsidy are measured as the percentage of months that beneficiaries meet the criteria in the year following the index date. Note: CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention, PDC stands for proportion of days covered.

Table 4.2. Regression Output Using Binary Health Literacy Variable

		M1: Probit Regression with Basic Controls	M2: Probit Regression with ADI & Rural	M3: IPTW with Basic Controls	M4: IPTW with ADI & Rural	M5: 2SRI with Basic Controls	M6: 2SRI with ADI & Rural
Variable	**Level**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**
Health Literacy	Low	-2.06% (1.09%)	-1.56% (1.13%)	-2.2% (1.43%)	-1.81% (1.78%)	-1.35% (1.14%)	-0.89% (1.2%)
	Med. Only	Reference					
Treatment	CABG	-3.9%*** (1.03%)	-3.93%*** (1.05%)	-4.01%*** (1.02%)	-4.32%** (1.27%)	19.62%** (7.44%)	20.07%** (7.7%)
	PCI	-1.54%* (0.71%)	-1.42% (0.73%)	-1.8%** (0.62%)	-1.65%* (0.77%)	-4.41% (9.03%)	-5.05% (9.26%)
Age Splines		Reference					
Cardiologists per 10K		0.0005 (0.007)	0.0078 (0.0076)	-0.0022 (0.0082)	0.0011 (0.0109)	0.0004 (0.0073)	0.008 (0.0076)
PCPs per 10K		0.0022 (0.0015)	0.0018 (0.0015)	0.0012 (0.0017)	0.0009 (0.0021)	0.0027 (0.0016)	0.0022 (0.0017)
Beds per 10K		-0.0001 (0.0001)	-0.0001 (0.0001)	-0.0001 (0.0001)	-0.0001 (0.0002)	-0.0001 (0.0001)	-0.0001 (0.0001)
Low Income Subsidy		0.17% (1.23%)	0.3% (1.27%)	0.33% (1.54%)	0.24% (2.01%)	0.54% (1.3%)	0.66% (1.34%)
Dual Eligible		-0.76% (1.38%)	-0.97% (1.41%)	-1.81% (1.83%)	-1.93% (2.39%)	0.21% (1.47%)	-0.02% (1.52%)
Partial Dual Eligible		-1.23% (1.58%)	-1.41% (1.62%)	-0.52% (1.93%)	-0.23% (2.58%)	-0.83% (1.62%)	-1.1% (1.57%)
Race	White	Reference					
	Black	-4.52%*** (1.25%)	-4.2%** (1.28%)	-1.92% (1.65%)	-1.43% (1.9%)	-3.79%** (1.29%)	-3.41%* (1.43%)
	Hispanic	-9.1%*** (1.51%)	-8.66%*** (1.53%)	-6.49%*** (1.74%)	-6.42%** (2.2%)	-9.92%*** (1.54%)	-9.44%*** (1.7%)
	Other	-3.27%* (1.63%)	-2.97% (1.65%)	-3.24% (2.22%)	-3.03% (2.94%)	-3.79%* (1.76%)	-3.45%* (1.64%)
Female		-3.16%*** (0.61%)	-3.05%*** (0.62%)	-2.95%*** (0.71%)	-2.59%** (0.88%)	-5.52%*** (1.18%)	-5.44%*** (1.23%)
Diabetes		2.38%*** (0.59%)	2.5%*** (0.6%)	1.18% (0.72%)	1.3% (0.88%)	1.55%* (0.73%)	1.68%* (0.77%)

		M1: Probit Regression with Basic Controls	M2: Probit Regression with ADI & Rural	M3: IPTW with Basic Controls	M4: IPTW with ADI & Rural	M5: 2SRI with Basic Controls	M6: 2SRI with ADI & Rural
Variable	**Level**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**
Charlson Comorbidity Index	0	Reference					
	1	-1.06% (0.74%)	-1.19% (0.76%)	-0.07% (0.92%)	0.16% (1.12%)	-1.27% (0.77%)	-1.35% (0.8%)
	2	0.59% (1%)	0.38% (1.02%)	-1.73% (1.33%)	-2% (1.7%)	0.23% (1.07%)	-0.05% (1.12%)
	3	2.58% (1.42%)	2.25% (1.45%)	0.79% (1.94%)	0.72% (2.12%)	2.56% (1.41%)	2.17% (1.46%)
	4+	0.53% (1.98%)	0.17% (2.01%)	1.08% (2.57%)	0.16% (3.42%)	1.33% (2%)	0.89% (1.89%)
Year	2007	Reference					
	2008	-0.72% (0.89%)	-0.44% (0.9%)	0.44% (1.07%)	0.51% (1.33%)	-0.78% (0.97%)	-0.51% (0.95%)
	2009	0.47% (0.98%)	0.41% (1%)	2.12% (1.22%)	1.56% (1.57%)	0.18% (1.04%)	0.22% (1.08%)
	2010	0% (1.06%)	0.6% (1.08%)	-0.55% (1.43%)	-0.06% (1.71%)	-0.21% (1.21%)	0.3% (1.24%)
	2011	1.46% (1.08%)	1.71% (1.1%)	2.2% (1.29%)	1.81% (1.64%)	1.29% (1.21%)	1.61% (1.09%)
	2012	5.34%*** (1.05%)	4.96%*** (1.08%)	4.79%*** (1.33%)	4.02%* (1.59%)	5.45%*** (1.12%)	5.07%*** (1.13%)
	2013	6.14%*** (0.95%)	6.46%*** (0.97%)	6.94%*** (1.14%)	6.98%*** (1.42%)	6.69%*** (0.96%)	7.03%*** (0.99%)
Rural			1.77%* (0.77%)		0.86% (1.17%)		1.9%* (0.74%)
ADI Category	High Depr.		-1.28% (0.93%)		-0.99% (1.41%)		-1.27% (0.99%)
Period		11.76%*** (0.32%)	11.75%*** (0.32%)	12.18%*** (0.7%)	12.16%*** (0.53%)	11.76%*** (0.3%)	11.75%*** (0.33%)

*** p<0.001, ** p<0.01, * p<0.05

Note: ME stands for marginal effect, SE stands for standard error, IPTW stands for inverse probability of treatment weighting, 2SRI stands for two-stage residual inclusion, CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention, ADI stands for area deprivation index, PCPs stands for primary care physicians.

Table 4.3. Sensitivity Analysis Stratified by Health Literacy Level

Treatment	Lowest Health Literacy Quartile (Q1)	Highest Health Literacy Quartile (Q4)
	ME (SE)	ME (SE)
Medication Only	Reference	
CABG	19.21% (14.50%)	15.80%* (13.16%)
PCI	-10.43% (17.43%)	-2.73%* (13.27%)

*** p<0.001, ** p<0.01, * p<0.05
Note: All analyses were done using the two-stage residual inclusion (2SRI) approach.

4.7. Figures

Figure 4.1. Sample Flow Diagram

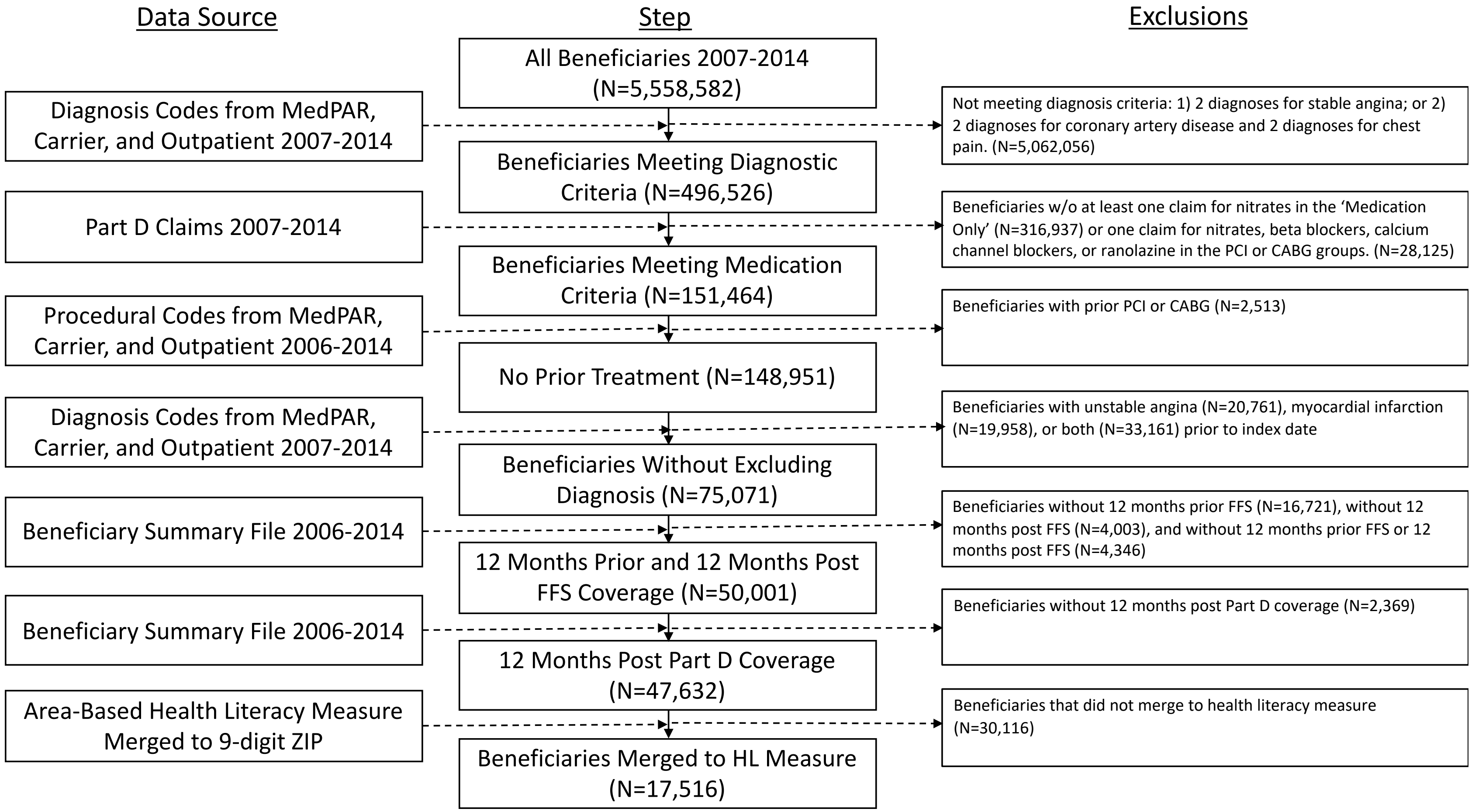


Figure 4.2. Propensity Score Density Plot for Receiving Medication Only

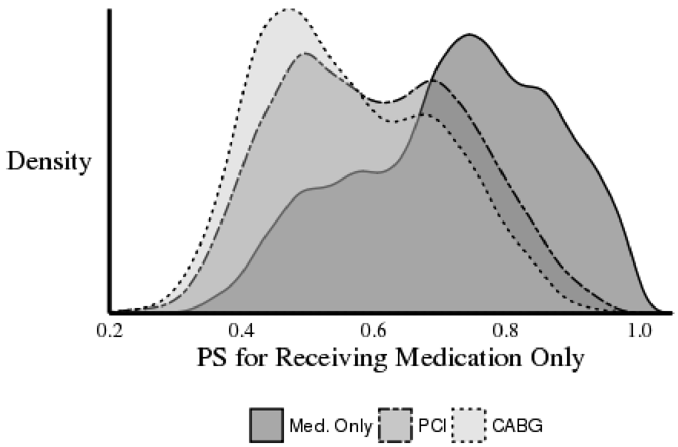


Figure 4.3. Propensity Score Density Plot for Receiving PCI

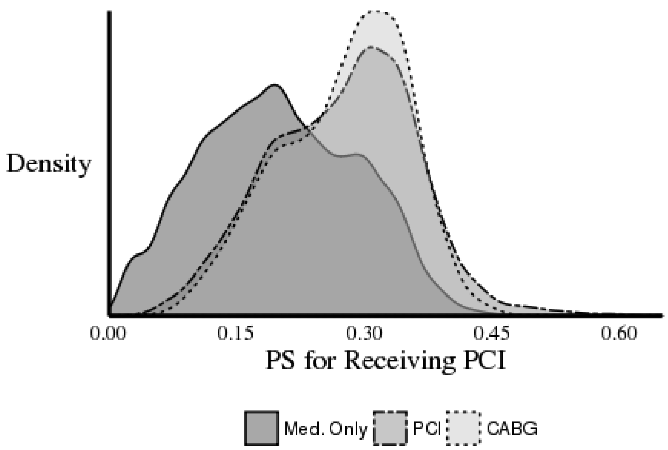
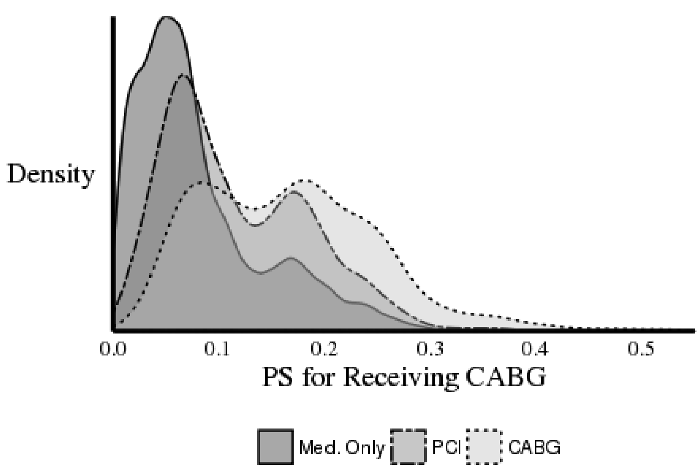
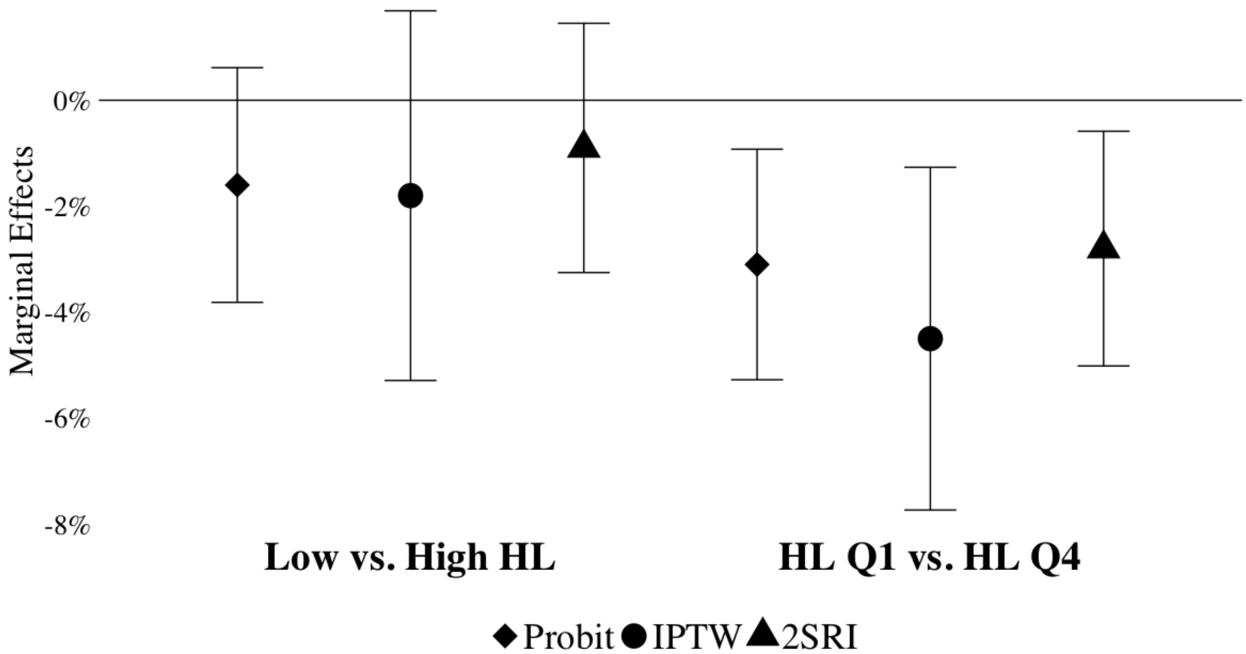


Figure 4.4. Propensity Score Density Plot for Receiving CABG



Note: PS stands for propensity score, PCI stands for percutaneous coronary intervention, CABG stands for coronary artery bypass grafting surgery.

Figure 4.5. Marginal Effects for Health Literacy



Note: IPTW stands for inverse probability of treatment weighting, 2SRI stands for two-stage residual inclusion, HL stands for health literacy. All models included ADI and rural status. Error bars show the 95% confidence interval.

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CHAPTER 5. CONCLUSIONS

5.1. Summary

The main objective of this dissertation was to assess the relationship of health literacy with key patient behaviors for the treatment of SAP. To our knowledge, the Chapter 2 analysis was first study to assess the relationship between area-based health literacy and treatment assignment for patients with SAP. The Chapter 3 analysis was the first study to characterize patient-clinician conversations to discuss treatment alternatives for SAP and assess health literacy as a potential barrier to communication in these conversations. The Chapter 4 analysis was the first study to assess the relationship between health literacy and medication adherence using an area-based measure for health literacy. The Chapter 2 and Chapter 4 analyses leveraged a large, national claims database to ensure a large sample size that was representative of elderly Medicare beneficiaries nationwide. The Chapter 3 analysis used a unique data source of recorded conversations between patients and clinicians to make sure the findings reflected actual clinical practice. The findings from these analyses help to inform potential interventions to improve patient-clinician discussions and medication adherence, particularly for patients with low health literacy.

5.1.1. Health Literacy and Treatment Assignment

The Chapter 2 analysis used multinomial logistic regression to assess the relationship between area-based health literacy and treatment assignment into medication only, PCI, or CABG. The data source was a 20 percent sample of Medicare claims for beneficiaries aged 65 years and older who had simultaneous enrollment in Medicare Parts A, B, and D. The study found that living in a low health literacy area relative to a high health literacy area was associated with a significant increase in the percentage of patients receiving medication only (2.9 percentage points) and a significant decrease in the percentage of patients receiving CABG (-3.0 percentage points). After adding controls for ADI and rural status, the marginal effect for living in a low health literacy area with respect to medication only become non-significant and the marginal effect with respect to CABG remained significant. The results for the quartile specification of health literacy differed somewhat. Living in the lowest quartile with respect to the highest quartile was still associated with significantly greater use of medication only. However, living in the lowest health literacy quartile was associated with significantly lower use of PCI but not CABG. In summary, these findings suggest that living in a low health literacy area was associated with greater use of the least invasive treatment alternative (medication only) and lower use of the two more invasive treatment alternatives (CABG and PCI).

The results supported the hypothesis that patients living in low health literacy communities may have had greater difficulty accessing PCI and CABG. Previous research has identified low health literacy as a predictor for reduced access to care.[1] The marginal effects for variables related to established predictors for worse access to care (rural status,[2] minority status[3], and low-income[4]) were generally in the same direction as the marginal effects for living in a low health literacy area. Typically, low access to care for patients is considered a problem since poor access to care is generally associated with worse health outcomes.[5] However, in the context of treatment of SAP, where outcomes are equivalent across more and less invasive treatment options for most patients, reduced access to PCI and CABG may actually be beneficial to patients. The study results contradicted our hypothesis that patients living in low health literacy areas would be more likely to receive more aggressive care, which would potentially be related to common misconceptions about the value of more invasive treatment for SAP.[6-8] Contrary to this hypothesis, patients living in low health literacy areas were actually less likely to receive PCI or CABG.

5.1.2. Characterization of Treatment Planning Discussions

The Chapter 3 analysis used a descriptive approach to characterize recorded patient-clinician interactions during treatment planning discussion for SAP. The analysis also assessed the potential role of health literacy as a barrier to communication. Health literacy was measured using a validated screening question.[9,10] The study found that patients tended to ask few questions about the clinical aspects of treatment alternatives (an average of one per discussion). Patients were more likely to ask questions about the logistics of treatment such as how long a procedure would take. Clinicians appeared to have similar approaches to communication for their patients. Some clinicians had consistently low shared decision-making and some had consistently high shared-decision making across multiple patients. This finding may be explained by either distinct clinician approaches to shared decision-making or the setting for the conversation (general cardiology clinic or cardiac catheterization lab). Finally, health literacy was associated with significantly greater decisional conflict, but not worse performance on the knowledge assessment or fewer questions asked during the conversations.

The results provide some support for health literacy as a potential barrier to communication, but the evidence was exploratory given the small sample size. Low health literacy was associated with greater decisional conflict following discussions. Low health literacy was not associated with worse performance on the knowledge assessment that tested patient understanding of the treatment alternatives. Low health literacy was also not associated with asking fewer questions or expressing fewer preferences during the conversations. The lack of statistical significance was partially due to the small sample size and small share of patients that were categorized as having low health literacy.

5.1.3. Health Literacy and Medication Adherence

The Chapter 4 analysis used probit regression, inverse probability of treatment weighting, and two-stage residual inclusion to assess the relationship between health literacy and mediation adherence to anti-anginal medications. The analysis also used the same 20 percent Medicare claims sample that was used in the Chapter 2 analysis. The study found that living in a low health literacy area was not associated with significantly worse adherence when using the dichotomous specification of health literacy. However, living in the lowest health literacy quartile relative to the highest quartile was associated with a significant decrease in medication adherence (-2.3 percentage points to -4.6 percentage points depending on the estimation method). While we found evidence that suggests there may be selection into treatment (Medication Only, PCI, or CABG), the results for health literacy appeared consistent across the different estimation methods. These results were consistent with the findings from previous systematic reviews that found inconclusive evidence[1,11] or only a small significant association between health literacy and medication adherence.[12]

5.2. Implications for Policy

The goal of this dissertation was to inform potential interventions that are sensitive to health literacy. The aims analyze treatment assignment and medication adherence, which involve patient and provider behaviors that may be associated with the patient's health literacy. Interventions exist to help ensure treatment assignment incorporates patient preferences (e.g., shared decision-making tools) and improve medication adherence (e.g., medication reminders). However, the gaps in the literature with respect to health literacy make it difficult to determine whether health literacy should be considered when developing these interventions. The dissertation research helps to address these gaps and inform the design for such interventions.

The results from Chapters 2 and 3 provided mixed evidence on the relationship for health literacy with treatment assignment and treatment planning discussions. Living in a low health literacy area was not associated with being more likely to receive more invasive treatment. For the treatment of SAP, the main concern has been that misconceptions about the value of PCI relative to medication only lead to lower than optimal use of medication only.[13,14] In addition, there were not statistically significant differences in the proportion of knowledge questions answered correctly by health literacy category. This finding also contradicts the hypothesis that misconceptions about the relative benefits of treatment alternatives are more prevalent among patients with low health literacy. Any educational interventions should be made available for all patients regardless of their health literacy status. Low health literacy was found to be significantly associated with greater decisional conflict. This finding provided some support for a need to ensure that patient-clinician communication is suitable for patients with limited health literacy skills. However, the limitations of the analysis (small sample size and single institution) means that more research confirming this result in other contexts may be needed before basing interventions around the finding. It is also possible that the greater decisional conflict may be associated with patients regretting the treatment that the patient selected with their clinician. In previous research, decisional conflict and decisional regret appear to be affected by similar factors[15,16] and it possible that higher decisional conflict may be associated with patients have greater decisional regret. This possibility would also need to be confirmed in additional research as the data for the Chapter 3 analysis did not include a measure of decisional regret.

The results from Chapter 2 suggested that patients with low health literacy had lower access to more interventional treatments. Although this lower receipt of interventional therapies may prove beneficial in the context of SAP, health systems may want to consider providing additional resources to communities with low area-based health literacy to improve access to care for conditions in which better access is tied to improved health outcomes. Having better access to care has been linked with better health outcomes for many conditions.[5] However, the relationship between area-based health literacy and access to care may be specific to treatment for SAP. As such, more research confirming these findings for other conditions are needed before designing interventions.

The results from Chapter 4 provided limited evidence on a relationship between area-based health literacy and medication adherence for patients with SAP. Across all estimation methods, living in a low health literacy area was not significantly associated with medication adherence. However, in the quartile specification living in the lowest health literacy quartile relative to the highest quartile was associated with worse medication adherence across all estimation methods. The magnitude of the marginal effect for this result ranged from small (-2.3 percentage points) to moderate (4.6 percentage points). Given that the results were sensitive the how the health literacy measure was specified (quartile or dichotomous) and the magnitude of the association was not large, the results suggest that area-level measures of health literacy are not an important factor in medication adherence. The magnitude of the marginal effects may have been stronger if an individual-level health literacy measure was available since there would be less error in categorizing individuals as low or high health literacy (assuming the area-based health literacy measure is being used as a proxy for individual health literacy). Further research would be necessary to confirm this possibility.

5.3. Limitations

This dissertation has several limitations that affect the interpretation of the results. First, the analyses for Chapters 2 and 4 used an area-based measure for health literacy and socioeconomic status. The area-based measure for literacy has been previously validated and was found to have fair agreement with several individual measures for health literacy (κ ranging from 0.38 to 0.40). Nevertheless, the use of the area-based measure was associated with greater error than individual measures for health literacy.[17] A particular concern is the ecological fallacy: The associations observed for patients living in areas with low health literacy may not hold for individuals within these communities who have low health literacy. A way to address the concerns about the ecological fallacy is to interpret the results as measuring community health literacy measures and not as a proxy for individual health literacy. Similar concerns exist for the ADI since it is also an area-based measure for socioeconomic status. The ADI can also be interpreted as measuring community SES to address concerns about the ecological fallacy. While interpreting the area-based measures in terms of community health literacy and SES partially address concerns about the ecological fallacy, the studies would have been stronger if we had been able to identify a data source with a large sample that also included individual measures for health literacy and SES. We initially attempted to use survey data linked with claims data from the Health and Retirement Study (HRS) that included individual measures for health literacy and SES. However, the sample size was too small to perform the analyses. We also assessed the Medicare Current Beneficiary Survey since these data would have measures beyond claims, but the sample size was similarly too small to be useful for analysis.

Second, many relevant clinical variables that affect treatment assignment for patients with SAP were not available. The claims did not have information on disease severity such as the extent of blockage and whether the patient had left main coronary artery disease. The claims also lacked information about anatomic variants in the coronary arteries. These factors change the relative tradeoffs for medication only, PCI, and CABG.[18] The claims data also lacked detailed information on the status of patient's symptoms. It is possible that patients received PCI or CABG in response to not receiving sufficient symptom relief from medication only. The lack of symptom information also prevented the analysis of whether patients reduced adherence to anti-anginals in response to improvements in symptom status.

Third, there were methodological concerns for the Chapters 2 and 4 analyses. In Chapter 2, multinomial logistic regression was used to model treatment assignment to medication only, PCI, or CABG. However, the independence of irrelevant alternatives (IIA) assumption was violated.[19] Violations of this assumption can lead to biased coefficients and marginal effects. In practice, violations of this assumption are often ignored. We attempted to assess this assumption by collapsing the three-category treatment variable to a dichotomous variable of medication only vs. PCI or CABG. The results were largely consistent with the analysis using the three-category variable. A better approach would have been to run a nested logit or multinomial probit with a more flexible error structure. These options could not be performed because we lacked alternative-specific variables in the data. In Chapter 4, we used an instrumental variable approach with 2SRI. For IV analyses that are exactly identified, the exclusion restriction assumption cannot be tested directly and can only be defended by theory. We noted a potential violation of this assumption in the discussion section of Chapter 4. In addition, there have recently been concerns about 2SRI producing biased results.[20] Because of this concern, we did not focus on interpreting the marginal effects for PCI and CABG, which varied widely when using the 2SRI estimation method.

Fourth, the Chapter 3 analysis used a small sample that may not be generalizable to the broader population. The full sample (N=118) and recording sample (N=53) were relatively small and an even smaller share of these samples were individuals categorized as having low health literacy via self-report (22/118 for the full sample and 10/53 for the recording sample). The small sample size meant that the statistical power for the analyses was relatively low. In addition, only one person who was a racial or ethnic minority was included in the sample and the conversations took place at the Mayo Clinic, which is a premier health system. As such, these results may not be generalizable to populations that include racial or ethnic minorities and to health systems that operate differently or draw from a different patient population than the Mayo Clinic. Limitations on generalizability and sample size are common for qualitative research since it is usually not feasible to conduct such analyses using large, representative samples.

Fifth, the health literacy measure for the Chapter 3 analysis relied on patient self-report. In the analysis, health literacy was assessed using a validated screening question: "How confident are you filling out healthcare forms by yourself?"[9,10] This screening question had good agreement when compared with instruments for measuring health literacy (REALM[21] and TOFHLA[22])[9,10] Nevertheless, there is more error in measuring health literacy with this screening question than with the instruments.[9,10]

Sixth, the area-based measure could only be merged with approximately 40 percent of the cases identified in the claims. This issue was due to the inability to geocode many of the 9-digit ZIP codes in the claims data with respect to the census block-group. We investigated whether the individuals who merged were similar to individuals who were not merged. We found no systematic differences in terms of demographic characteristics. However, it is possible that these groups differed on unobservable characteristics.

5.4. Future Research Directions

As the number of individuals with low health literacy grows in the coming years,[23] it will become increasingly important to understand how health literacy affects key patient behaviors. This dissertation research contributes to the evidence base on this issue and lays the groundwork for further research.

The dissertation provided additional evidence on the viability of using an area-based measure for health literacy. We found that the area-based health literacy measure could be successfully merged with a Medicare claims sample. The area-based health literacy measure could be applied to the treatment for other diseases such as diabetes or cancer. In particular, analyses could examine whether living in a low health literacy area is associated with worse access to care for other conditions. The Chapter 2 results suggested that there was a relationship between living in a low health literacy area and worse access to care. While lower access to care may be beneficial for the treatment of SAP, for other conditions poor access to care is a predictor of worse health outcomes.[5] For such conditions, it may be valuable to understand whether living in a low health literacy areas is a barrier to access. This research could inform interventions to improve access to care for these conditions among patients living in a low health literacy community.

The Chapter 4 analysis could be re-analyzed using alternative estimation methods and ways of specifying the period over which adherence is measured to address limitations. As noted, there are concerns about the use of 2SRI.[20] One way to address these concerns would be to use alternative residual specifications as sensitivity analyses. The Chapter 4 analysis used only the raw residuals, but other residual specification can be evaluated. These approaches include the standardized residuals, deviance residuals, Anscombe residuals, and generalized residuals.[20] Appendix Tables 19 and 20 shows the results for two of these residual specifications. The results for both dichotomous and quartile health literacy were similar across the different residual specifications. The future work will extend to include the other residual specifications. Another concern was that the period over which adherence was measured included days before patients received PCI or CABG. The reason for this issue was that the period started on the date of the first diagnosis for SAP and treatment group was defined based on whether the patient received either PCI or CABG at any point during the period. An alternative approach would be to exclude the first six months after diagnosis from the adherence period and define treatment groups based on whether the patient received PCI or CABG within the first six months. This approach would ensure that the adherence measure does not include days before the patient received a procedure. Patients who received PCI or CABG after the first six months and before the end of the adherence period would be excluded from the analysis. Appendix Figures 1 and 2 show that most patients received PCI or CABG within the first six months following diagnosis. As such, only a small proportion of patients who received PCI or CABG would need to be dropped.

The Chapter 4 analysis could be extended to examine other medications for SAP or medications for other conditions. The analysis only examined medication adherence for anti-anginal medications. The analysis could also include other medications that patients take for coronary artery disease including anti-platelet therapy, ACE inhibitors, and statins. An advantage of examining these medications is that they impact health outcomes, whereas anti-anginal medications are primarily used for symptom relief.[18] As such, the behavioral response may be different for these medications. This analysis could also be applied to medication adherence for other chronic conditions such as hypertension and diabetes.

Lastly, the Chapter 4 analytical approach could be applied to outcomes for SAP other than medication adherence. In particular, the analyses could examine the relationship of area-based health literacy and treatment assignment with health outcomes after controlling for selection into treatment. Important health outcomes for these patients that are available in the claims data include myocardial infarction, cardiovascular death, and emergency room visits or inpatient admissions related to coronary artery disease.

5.5. Conclusion

In summary, this dissertation provided evidence on how health literacy is related to treatment assignment, discussion quality, and medication adherence. In this dissertation, we found that: 1) living in low health literacy areas was associated with lower utilization of more invasive treatment (PCI and CABG), 2) low health literacy may act as a potential barrier to patient-clinician communication, and 3) living in low health literacy areas was associated with worse medication adherence but the evidence was limited and depended on how the health literacy variable was specified. These findings have implications for the importance of considering health literacy in analyzing treatment assignment and medication adherence. The results also support a broad need for interventions to improve communication to make it more suitable for all patients, but especially those with low health literacy.

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APPENDIX 1. APPENDIX TABLES FOR CHAPTER 2

Appendix Table 1. Diagnostic Algorithms for Identifying Stable Angina Pectoris

Algorithm	Diagnostic Criteria	Medication Criteria
1	• 2 claims with diagnoses for stable angina pectoris	• 2 claims for nitrates for medical therapy • No claims for nitrates required for PCI or CABG
2	• 2 claims with diagnoses for coronary artery disease • 2 claims with diagnoses for chest pain	• 2 claims for nitrates for medical therapy • No claims for nitrates required for PCI or CABG

Adapted from Kempf et al. 2011. Note that medication use was not required for patients receiving PCI or CABG because receiving a procedure was considered sufficient evidence that the patient had stable angina pectoris.

Appendix Table 2. International Classification of Diseases, Ninth Revision 4

Diagnosis	ICD-9 Codes
Stable angina pectoris	413.0, 413.1, 413.9
Coronary artery disease	411.0, 411.1, 411.8, 411.81, 411.89, 414.00, 414.01, 414.02, 414.03, 414.04, 414.05, 414.06, 414.07, 414.10, 414.11, 414.12, 414.19, 414.2, 414.3, 414.8, 414.9, 429.2, 429.6, 429.71, 429.79, 996.03, V45.81, V45.82
Chest pain	786.51, 785.52, 786.59
Myocardial infarction	410.0, 410.1, 410.2, 410.3, 410.4, 410.5, 410.6, 410.7, 410.8, 410.00, 410.01, 410.02, 410.10, 410.11, 410.12, 410.20, 410.21, 410.22, 410.30, 410.31, 410.32, 410.40, 410.41, 410.42, 410.50, 410.51, 410.52, 410.60, 410.61, 410.62, 410.70, 410.71, 410.72, 410.80, 410.81, 410.82, 410.90, 410.91, 410.92, 412"
Unstable angina pectoris	411.1
Diabetes	249.01, 249.10, 249.11, 249.20, 249.21, 249.30, 249.31, 249.40, 249.41, 249.50, 249.51, 249.60, 249.61, 249.70, 249.71, 249.80, 249.81, 249.90, 249.91, 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93

Appendix Table 3. Procedural Codes

Procedure	Code Type	Codes
PCI	CPT (pre 2013)	92980, 92981, 92982, 92983, 92984, 92995, 92996
	CPT (post 2013)	92920, 92921, 92924, 92925, 92928, 92929, 92933, 92934, 92937, 92938
	ICD-9 Procedure	00.66, 36.06, 36.01, 36.02, 36.05, 36.09
	DRG (pre 2008)	518, 555, 556, 557, 558
	DRG (post 2008)	246, 247, 248, 249, 250, 251
CABG	CPT	33510, 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33520, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536
	ICD-9 Procedure	36.1, 36.10, 36.11, 36.12, 36.13, 36.14, 36.15, 36.16, 36.17, 36.19
	DRG (pre 2008)	106, 547, 548, 549, 550
	DRG (post 2008)	231, 232, 233, 234, 235, 236

Note: CABG stands for coronary artery bypass graft surgery, CPT stands for current procedural terminology, DRG stands for diagnosis related group, PCI stands for percutaneous coronary intervention.

Appendix Table 4. Descriptive Statistics by Health Literacy Quartile

Variable	Level	Q1 (Low HL) N=3,036 Freq (Pct)	Q2 N=4,582 Freq (Pct)	Q3 N=4,085 Freq (Pct)	Q4 (High HL) N=3,732 Freq (Pct)
	Medical therapy	1,699 (56.0%)	2,284 (49.8%)	1,933 (47.3%)	1,589 (42.6%)
Treatment Received	CABG	397 (13.1%)	735 (16.0%)	669 (16.4%)	662 (17.7%)
	PCI	940 (31.0%)	1,563 (34.1%)	1,483 (36.3%)	1,481 (39.7%)
	Male	1,791 (59.0%)	2,548 (55.6%)	2,124 (52.0%)	1,760 (47.2%)
Sex	Female	1,245 (41.0%)	2,034 (44.4%)	1,961 (48.0%)	1,972 (52.8%)
	65-70	894 (29.4%)	1,210 (26.4%)	1,042 (25.5%)	926 (24.8%)
	70-75	655 (21.6%)	1,031 (22.5%)	911 (22.3%)	811 (21.7%)
Age	75-80	596 (19.6%)	882 (19.2%)	836 (20.5%)	734 (19.7%)
	80+	891 (29.3%)	1,459 (31.8%)	1,296 (31.7%)	1,261 (33.8%)
	Male	1,468 (48.4%)	4,085 (89.2%)	3,826 (93.7%)	3,527 (94.5%)
	Female	856 (28.2%)	216 (4.7%)	67 (1.6%)	44 (1.2%)
Sex	White	537 (17.7%)	137 (3.0%)	92 (2.3%)	43 (1.2%)
	Black	175 (5.8%)	144 (3.1%)	100 (2.4%)	118 (3.2%)
	No	1,457 (48.0%)	2,589 (56.5%)	2,343 (57.4%)	2,312 (62.0%)
Diabetes	Yes	1,579 (52.0%)	1,993 (43.5%)	1,742 (42.6%)	1,420 (38.0%)
	0	1,797 (59.2%)	2,812 (61.4%)	2,636 (64.5%)	2,568 (68.8%)
	1	633 (20.8%)	1,000 (21.8%)	860 (21.1%)	704 (18.9%)
Charlson Comorbidity Index	2	357 (11.8%)	456 (10.0%)	352 (8.6%)	281 (7.5%)
	3	162 (5.3%)	185 (4.0%)	155 (3.8%)	119 (3.2%)
	4+	87 (2.9%)	129 (2.8%)	82 (2.0%)	60 (1.6%)
	2007	955 (31.5%)	1,306 (28.5%)	1,023 (25.0%)	879 (23.6%)
	2008	592 (19.5%)	845 (18.4%)	778 (19.0%)	612 (16.4%)
	2009	379 (12.5%)	593 (12.9%)	552 (13.5%)	521 (14.0%)
	2010	319 (10.5%)	474 (10.3%)	430 (10.5%)	428 (11.5%)
Year	2011	254 (8.4%)	423 (9.2%)	396 (9.7%)	377 (10.1%)
	2012	243 (8.0%)	429 (9.4%)	374 (9.2%)	387 (10.4%)
	2013	294 (9.7%)	512 (11.2%)	532 (13.0%)	528 (14.1%)
	Q1 (Low Depr.)	308 (10.5%)	595 (13.7%)	929 (23.6%)	2,131 (58.6%)
	Q2	512 (17.5%)	836 (19.3%)	1,285 (32.6%)	1,012 (27.8%)
ADI Quartiles	Q3	641 (21.9%)	1,500 (34.6%)	1,237 (31.4%)	394 (10.8%)
	Q4 (High Depr.)	1,465 (50.1%)	1,402 (32.4%)	491 (12.5%)	97 (2.7%)
	Urban	2,384 (78.5%)	2,698 (58.9%)	3,013 (73.8%)	3,407 (91.3%)
Rural Status	Rural	652 (21.5%)	1,884 (41.1%)	1,072 (26.2%)	325 (8.7%)
Variable		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Cardiologists per 10K Residents		0.72 (0.54)	0.53 (0.52)	0.63 (0.57)	0.86 (0.68)
PCPs per 10K Residents		6.88 (2.56)	6.47 (2.73)	7.10 (2.76)	8.21 (2.94)
Beds per 10K Residents		36.24 (25.57)	34.15 (30.59)	33.37 (23.83)	33.45 (23.38)
Full Dual Eligible		37.1% (47.3%)	19.0% (38.4%)	12.0% (31.6%)	8.6% (27.4%)
Partial Dual Eligible		10.0% (28.8%)	7.9% (25.9%)	5.7% (22.1%)	2.6% (15.3%)
Low Income Subsidy		54.2% (49.4%)	32.3% (46.4%)	22.0% (41.0%)	13.6% (34.0%)
Percent Receiving PCI		34.6% (9.3%)	35.3% (9.4%)	35.1% (9.9%)	35.3% (9.9%)
Percent Receiving CABG		14.5% (5.5%)	15.0% (5.6%)	15.0% (5.8%)	15.1% (5.7%)

*Full dual eligible, partial dual eligible, and receives Low Income Subsidy are measured as the percentage of months that beneficiaries meet the criteria in the year following the index date.

Note: CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary intervention

Appendix Table 5. Marginal Effects for Quartile Specification

Variables	Level	Bivariate	Basic Controls	Basic Controls, Rural, ADI	Controls, Treatment Patterns	Controls, Rural, ADI, Treatment Patterns
		Medical therapy				
Health Literacy Quartiles	Q1 (Low HL)	13.38%***	5.19%***	3.57%*	4.98%***	3.54%*
		(1.21%)	(1.31%)	(1.50%)	(1.31%)	(1.50%)
	Q2	7.27%***	3.62%***	2.24%	3.64%***	2.43%*
		(1.10%)	(1.06%)	(1.20%)	(1.06%)	(1.20%)
	Q3	4.74%***	3.21%**	2.04%	3.23%**	2.19%*
		(1.12%)	(1.04%)	(1.11%)	(1.04%)	(1.11%)
	Q4 (High HL)	Reference				
Rural & ADI				✓		✓
Percent Receiving PCI & CABG					✓	✓
		PCI				
Health Literacy Quartiles	Q1 (Low HL)	-8.72%***	-4.41%***	-3.38%*	-4.25%**	-3.37%*
		(1.16%)	(1.33%)	(1.53%)	(1.33%)	(1.53%)
	Q2	-5.57%***	-3.43%**	-2.81%*	-3.43%**	-2.99%*
		(1.06%)	(1.08%)	(1.22%)	(1.08%)	(1.22%)
	Q3	-3.38%**	-2.38%*	-1.44%	-2.42%*	-1.60%
		(1.10%)	(1.06%)	(1.13%)	(1.06%)	(1.13%)
	Q4 (High HL)	Reference				
Rural & ADI				✓		✓
Percent Receiving PCI & CABG					✓	✓
		CABG				
Health Literacy Quartiles	Q1 (Low HL)	-4.66%***	-0.77%	-0.19%	-0.73%	-0.17%
		(0.87%)	(1.04%)	(1.18%)	(1.04%)	(1.18%)
	Q2	-1.70%*	-0.20%	0.57%	-0.21%	0.56%
		(0.83%)	(0.83%)	(0.93%)	(0.82%)	(0.93%)
	Q3	-1.36%	-0.82%	-0.60%	-0.82%	-0.59%
		(0.85%)	(0.80%)	(0.85%)	(0.80%)	(0.84%)
	Q4 (High HL)	Reference				
Rural & ADI				✓		✓
Percent Receiving PCI & CABG					✓	✓
Observations		15,435	15,435	14,835	15,435	14,835

Standard errors in parentheses. *** p<0.001, ** p<0.01, * p<0.05.

Note: ADI stands for area deprivation index. CABG stands for coronary artery bypass grafting, HL stands for health literacy, PCI stands for percutaneous coronary intervention.

Appendix Table 6. Full Model Marginal Effects for Multinomial Logistic Regression with Quartile Specification of Health Literacy Variable

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
Variables	**Level**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**
				MEDS		
Health Literacy Quartiles	Q1 (Low HL)	13.38%***	5.19%***	3.57%*	4.98%***	3.54%*
		(1.21%)	(1.31%)	(1.50%)	(1.31%)	(1.50%)
	Q2	7.27%***	3.62%***	2.24%	3.64%***	2.43%*
		(1.10%)	(1.06%)	(1.20%)	(1.06%)	(1.20%)
	Q3	4.74%***	3.21%**	2.04%	3.23%**	2.19%*
		(1.12%)	(1.04%)	(1.11%)	(1.04%)	(1.11%)
	Q4 (High HL)			Reference		
Age Cubic Splines						
Cardiologists per 10K Residents			-1.64%	-1.16%	-1.41%	-1.04%
			(1.01%)	(1.07%)	(1.00%)	(1.06%)
Primary Care Physicians per 10K Residents			0.16%	0.24%	0.14%	0.21%
			(0.21%)	(0.21%)	(0.21%)	(0.21%)
Beds per 10K Residents			0.02%	0.02%	0.02%	0.01%
			(0.02%)	(0.02%)	(0.02%)	(0.02%)
Receives Low Income Subsidy			6.03%***	5.49%***	6.00%***	5.48%***
			(1.60%)	(1.64%)	(1.59%)	(1.63%)
Full Dual Eligible			15.34%***	15.96%***	15.04%***	15.68%***
			(1.83%)	(1.87%)	(1.82%)	(1.86%)
Partial Dual Eligible			4.00%	4.81%*	3.75%	4.54%*
			(2.05%)	(2.10%)	(2.04%)	(2.10%)
Race	White			Reference		
	Black		10.11%***	10.48%***	9.78%***	10.12%***
			(1.61%)	(1.65%)	(1.61%)	(1.64%)
	Hispanic		-6.45%***	-6.45%***	-6.41%***	-6.45%***
			(1.77%)	(1.80%)	(1.77%)	(1.80%)
	Other		3.00%	3.90%	2.64%	3.47%
			(2.16%)	(2.20%)	(2.16%)	(2.20%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
Female			-12.34%***	-11.96%***	-12.28%***	-11.91%***
			(0.77%)	(0.78%)	(0.77%)	(0.78%)
Diabetes			-4.84%***	-5.27%***	-4.86%***	-5.28%***
			(0.75%)	(0.77%)	(0.75%)	(0.76%)
Charlson Comorbidity Index	0			Reference		
	1		-2.09%*	-1.88%*	-2.02%*	-1.81%
			(0.93%)	(0.95%)	(0.93%)	(0.95%)
	2		1.55%	1.42%	1.59%	1.50%
			(1.30%)	(1.32%)	(1.30%)	(1.32%)
	3		6.42%***	6.21%**	6.42%***	6.21%**
			(1.95%)	(1.97%)	(1.94%)	(1.96%)
	4+		14.15%***	13.81%***	14.10%***	13.76%***
			(2.55%)	(2.59%)	(2.55%)	(2.59%)
Year	2007			Reference		
	2008		-2.72%*	-2.72%*	-1.28%	-1.26%
			(1.11%)	(1.13%)	(1.12%)	(1.14%)
	2009		-7.46%***	-7.00%***	-4.75%***	-4.29%***
			(1.23%)	(1.25%)	(1.27%)	(1.29%)
	2010		-8.03%***	-7.97%***	-4.60%***	-4.53%**
			(1.32%)	(1.35%)	(1.39%)	(1.42%)
	2011		-5.74%***	-5.17%***	-2.51%	-1.91%
			(1.39%)	(1.42%)	(1.44%)	(1.47%)
	2012		-0.86%	-0.96%	1.45%	1.37%
			(1.41%)	(1.43%)	(1.42%)	(1.45%)
	2013		4.71%***	4.88%***	7.00%***	7.18%***
			(1.30%)	(1.33%)	(1.32%)	(1.35%)
State Fixed Effects						
Rural				2.70%*		2.38%*
				(1.06%)		(1.06%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
ADI Quartiles	Q1 (Low Deprivation			Reference		
	Q2			2.00%		1.76%
				(1.15%)		(1.15%)
	Q3			3.04%*		2.67%*
				(1.29%)		(1.29%)
	Q4 (High Deprivation)			2.19%		1.85%
				(1.49%)		(1.49%)
Percent Receiving CABG					-0.28%***	-0.28%***
					(0.07%)	(0.07%)
Percent Receiving PCI					-0.36%***	-0.35%***
					(0.04%)	(0.05%)
PCI						
Health Literacy Quartiles	Q1 (Low HL)	-8.72%***	-4.41%***	-3.38%*	-4.25%**	-3.37%*
		(1.16%)	(1.33%)	(1.53%)	(1.33%)	(1.53%)
	Q2	-5.57%***	-3.43%**	-2.81%*	-3.43%**	-2.99%*
		(1.06%)	(1.08%)	(1.22%)	(1.08%)	(1.22%)
	Q3	-3.38%**	-2.38%*	-1.44%	-2.42%*	-1.60%
		(1.10%)	(1.06%)	(1.13%)	(1.06%)	(1.13%)
	Q4 (High HL)			Reference		
Age Cubic Splines						
Cardiologists per 10K Residents			1.61%	1.78%	1.39%	1.66%
			(1.02%)	(1.08%)	(1.02%)	(1.08%)
Primary Care Physicians per 10K Residents			-0.15%	-0.23%	-0.12%	-0.18%
			(0.21%)	(0.22%)	(0.21%)	(0.22%)
Beds per 10K Residents			-0.01%	-0.01%	-0.00%	-0.00%
			(0.02%)	(0.02%)	(0.02%)	(0.02%)
Receives Low Income Subsidy			-4.24%*	-3.93%*	-4.20%*	-3.90%*
			(1.68%)	(1.71%)	(1.67%)	(1.71%)
Full Dual Eligible			-8.64%***	-9.22%***	-8.39%***	-9.00%***
			(1.98%)	(2.01%)	(1.97%)	(2.01%)
Partial Dual Eligible			-3.21%	-4.00%	-2.90%	-3.68%
			(2.17%)	(2.22%)	(2.16%)	(2.22%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
Race	White			Reference		
	Black		-3.69%*	-3.93%*	-3.38%*	-3.57%*
			(1.61%)	(1.64%)	(1.61%)	(1.64%)
	Hispanic		2.19%	2.52%	2.16%	2.51%
			(1.97%)	(2.00%)	(1.96%)	(1.99%)
	Other		-2.62%	-2.99%	-2.37%	-2.67%
			(2.21%)	(2.23%)	(2.21%)	(2.23%)
Female			3.30%***	3.03%***	3.23%***	2.97%***
			(0.77%)	(0.79%)	(0.77%)	(0.78%)
Diabetes			1.34%	1.85%*	1.36%	1.85%*
			(0.77%)	(0.78%)	(0.77%)	(0.78%)
Charlson Comorbidity Index	0			Reference		
	1		1.45%	1.53%	1.39%	1.47%
			(0.96%)	(0.98%)	(0.96%)	(0.98%)
	2		-3.08%*	-3.11%*	-3.12%*	-3.18%*
			(1.32%)	(1.34%)	(1.32%)	(1.34%)
	3		-5.25%**	-5.31%**	-5.26%**	-5.33%**
			(1.93%)	(1.96%)	(1.93%)	(1.95%)
	4+		-8.59%***	-8.68%***	-8.58%***	-8.68%***
			(2.50%)	(2.54%)	(2.50%)	(2.53%)
Year	2007			Reference		
	2008		3.34%**	3.38%**	2.18%	2.22%
			(1.13%)	(1.15%)	(1.16%)	(1.18%)
	2009		6.48%***	6.45%***	4.10%**	4.09%**
			(1.27%)	(1.29%)	(1.31%)	(1.34%)
	2010		6.37%***	6.00%***	3.27%*	2.93%*
			(1.37%)	(1.40%)	(1.43%)	(1.45%)
	2011		5.08%***	4.84%***	2.15%	1.92%
			(1.42%)	(1.45%)	(1.47%)	(1.49%)
	2012		1.41%	1.57%	-0.65%	-0.49%
			(1.41%)	(1.43%)	(1.43%)	(1.46%)
	2013		-1.04%	-1.20%	-3.03%*	-3.18%*
			(1.28%)	(1.30%)	(1.31%)	(1.34%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
State Fixed Effects						
Rural				-0.79%		-0.46%
				(1.07%)		(1.07%)
ADI Quartiles	Q1 (Low Deprivation			Reference		
	Q2			-1.12%		-0.86%
				(1.17%)		(1.16%)
	Q3			-2.33%		-1.94%
				(1.31%)		(1.31%)
	Q4 (High Deprivation)			-1.28%		-1.00%
				(1.53%)		(1.52%)
Percent Receiving CABG					0.12%	0.12%
					(0.07%)	(0.07%)
Percent Receiving PCI					0.37%***	0.36%***
					(0.05%)	(0.05%)
CABG						
Health Literacy Quartiles	Q1 (Low HL)	-4.66%***	-0.77%	-0.19%	-0.73%	-0.17%
		(0.87%)	(1.04%)	(1.18%)	(1.04%)	(1.18%)
	Q2	-1.70%*	-0.20%	0.57%	-0.21%	0.56%
		(0.83%)	(0.83%)	(0.93%)	(0.82%)	(0.93%)
	Q3	-1.36%	-0.82%	-0.60%	-0.82%	-0.59%
		(0.85%)	(0.80%)	(0.85%)	(0.80%)	(0.84%)
	Q4 (High HL)			Reference		
Age Cubic Splines						
Cardiologists per 10K Residents			0.02%	-0.63%	0.02%	-0.62%
			(0.81%)	(0.88%)	(0.80%)	(0.87%)
Primary Care Physicians per 10K Residents			-0.01%	-0.01%	-0.02%	-0.02%
			(0.16%)	(0.17%)	(0.16%)	(0.17%)
Beds per 10K Residents			-0.02%	-0.01%	-0.02%	-0.01%
			(0.01%)	(0.01%)	(0.01%)	(0.01%)
Receives Low Income Subsidy			-1.79%	-1.56%	-1.80%	-1.57%
			(1.33%)	(1.36%)	(1.33%)	(1.36%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
Full Dual Eligible			-6.71%***	-6.74%***	-6.66%***	-6.69%***
			(1.63%)	(1.65%)	(1.63%)	(1.65%)
Partial Dual Eligible			-0.79%	-0.81%	-0.85%	-0.86%
			(1.73%)	(1.77%)	(1.73%)	(1.77%)
Race	White		Reference			
	Black		-6.41%***	-6.54%***	-6.41%***	-6.54%***
			(1.08%)	(1.09%)	(1.08%)	(1.09%)
	Hispanic		4.26%*	3.93%*	4.25%*	3.94%*
			(1.70%)	(1.71%)	(1.70%)	(1.71%)
	Other		-0.38%	-0.91%	-0.27%	-0.79%
			(1.73%)	(1.72%)	(1.74%)	(1.73%)
Female			9.04%***	8.93%***	9.05%***	8.94%***
			(0.59%)	(0.60%)	(0.59%)	(0.60%)
Diabetes			3.50%***	3.42%***	3.50%***	3.43%***
			(0.60%)	(0.60%)	(0.59%)	(0.60%)
Charlson Comorbidity Index	0		Reference			
	1		0.64%	0.34%	0.64%	0.34%
			(0.75%)	(0.76%)	(0.75%)	(0.76%)
	2		1.53%	1.69%	1.53%	1.68%
			(1.07%)	(1.09%)	(1.07%)	(1.09%)
	3		-1.17%	-0.90%	-1.15%	-0.89%
			(1.52%)	(1.54%)	(1.52%)	(1.54%)
	4+		-5.56%**	-5.13%**	-5.52%**	-5.09%**
			(1.79%)	(1.84%)	(1.80%)	(1.84%)
Year	2007		Reference			
	2008		-0.62%	-0.66%	-0.90%	-0.96%
			(0.88%)	(0.89%)	(0.89%)	(0.91%)
	2009		0.98%	0.56%	0.66%	0.20%
			(0.99%)	(1.01%)	(1.03%)	(1.04%)
	2010		1.65%	1.98%	1.33%	1.60%
			(1.08%)	(1.10%)	(1.13%)	(1.16%)
	2011		0.67%	0.34%	0.35%	-0.01%
			(1.11%)	(1.12%)	(1.15%)	(1.17%)
	2012		-0.55%	-0.61%	-0.80%	-0.88%
			(1.09%)	(1.10%)	(1.11%)	(1.13%)

		M6: Bivariate	M7: Basic Controls	M8: Basic Controls, Rural, ADI	M9: Basic Controls, Treatment Patterns	M10: Basic Controls, Rural, ADI, Treatment Patterns
	2013		-3.67%***	-3.67%***	-3.97%***	-4.00%***
			-0.62%	-0.66%	-0.90%	-0.96%
State Fixed Effects			(0.95%)	(0.97%)	(0.98%)	(1.00%)
Rural				-1.90%*		-1.92%*
				(0.80%)		(0.80%)
ADI Quartiles	Q1 (Low Deprivation			Reference		
	Q2			-0.88%		-0.90%
				(0.90%)		(0.89%)
	Q3			-0.71%		-0.73%
				(1.02%)		(1.02%)
	Q4 (High Deprivation)			-0.90%		-0.86%
				(1.19%)		(1.19%)
Percent Receiving CABG					0.16%**	0.17%**
					(0.05%)	(0.06%)
Percent Receiving PCI					-0.01%	-0.01%
					(0.04%)	(0.04%)
Observations		15,435	15,435	14,835	15,435	14,835

Standard errors in parentheses. *** p<0.001, ** p<0.01, * p<0.05.

Appendix Table 7. Full Model Marginal Effects for Multinomial Logistic Regression with Dichotomous Specification of Health Literacy Variable

Variables	Level	M1: Bivariate	M2: Basic Controls	M3: Basic Controls, Rural, ADI	M4: Basic Controls, Treatment Patterns	M5: Basic Controls, Rural, ADI, Treatment Patterns
		ME (SE)	ME (SE)	ME (SE)	ME (SE)	ME (SE)
			MEDS			
Low Health Literacy (Basic/Below Basic)		11.86%***	3.33%*	3.36%*	2.94%*	2.90%
		(1.29%)	(1.45%)	(1.51%)	(1.44%)	(1.50%)
Age Cubic Splines						
Cardiologists per 10K Residents			-1.94%	-1.34%	-1.71%	-1.21%
			(1.01%)	(1.07%)	(1.00%)	(1.06%)
Primary Care Physicians per 10K Residents			0.09%	0.12%	0.07%	0.10%
			(0.21%)	(0.21%)	(0.20%)	(0.21%)
Beds per 10K Residents			0.03%	0.02%	0.02%	0.02%
			(0.02%)	(0.02%)	(0.02%)	(0.02%)
Receives Low Income Subsidy			6.41%***	5.91%***	6.39%***	5.88%***
			(1.60%)	(1.63%)	(1.59%)	(1.63%)
Full Dual Eligible			15.35%***	15.99%***	15.05%***	15.71%***
			(1.83%)	(1.87%)	(1.83%)	(1.86%)
Partial Dual Eligible			4.05%*	4.91%*	3.79%	4.62%*
			(2.05%)	(2.11%)	(2.04%)	(2.10%)
Race	White			Reference		
	Black		10.26%***	10.49%***	10.00%***	10.20%***
			(1.64%)	(1.68%)	(1.64%)	(1.67%)
	Hisp.		-6.66%***	-6.80%***	-6.57%***	-6.73%***
			(1.80%)	(1.83%)	(1.80%)	(1.83%)
	Other		3.01%	3.48%	2.65%	3.12%
			(2.16%)	(2.19%)	(2.16%)	(2.19%)
Female			-12.44%***	-12.10%***	-12.38%***	-12.05%***
			(0.77%)	(0.78%)	(0.77%)	(0.78%)
Diabetes			-4.76%***	-5.16%***	-4.78%***	-5.18%***
			(0.75%)	(0.77%)	(0.75%)	(0.76%)
Charlson Comorbidity Index	0			Reference		
	1		-2.07%*	-1.84%	-2.00%*	-1.77%
			(0.93%)	(0.95%)	(0.93%)	(0.95%)
	2		1.65%	1.52%	1.69%	1.60%
			(1.30%)	(1.32%)	(1.30%)	(1.32%)
	3		6.48%***	6.28%**	6.48%***	6.28%**

Variables	Level	M1: Bivariate	M2: Basic Controls	M3: Basic Controls, Rural, ADI	M4: Basic Controls, Treatment Patterns	M5: Basic Controls, Rural, ADI, Treatment Patterns
			(1.95%)	(1.97%)	(1.94%)	(1.97%)
			14.26%***	14.04%***	14.20%***	13.98%***
	4+		(2.55%)	(2.59%)	(2.55%)	(2.59%)
Year	2007		Reference			
	2008		-2.67%*	-2.68%*	-1.23%	-1.21%
			(1.11%)	(1.13%)	(1.12%)	(1.14%)
	2009		-7.53%***	-7.10%***	-4.84%***	-4.38%***
			(1.23%)	(1.25%)	(1.27%)	(1.29%)
	2010		-8.06%***	-8.01%***	-4.65%***	-4.55%**
			(1.33%)	(1.35%)	(1.39%)	(1.42%)
	2011		-5.75%***	-5.13%***	-2.53%	-1.87%
			(1.39%)	(1.42%)	(1.44%)	(1.47%)
	2012		-0.88%	-1.00%	1.41%	1.34%
			(1.41%)	(1.44%)	(1.42%)	(1.45%)
	2013		4.70%***	4.91%***	6.98%***	7.21%***
			(1.30%)	(1.33%)	(1.32%)	(1.35%)
State Fixed Effects						
Rural				3.43%***		3.09%**
				(1.03%)		(1.03%)
ADI High Deprivation				0.10%		0.17%
				(1.21%)		(1.20%)
Percent Receiving CABG					-0.28%***	-0.28%***
					(0.07%)	(0.07%)
Percent Receiving PCI					-0.36%***	-0.36%***
					(0.04%)	(0.05%)
PCI						
Low Health Literacy (Basic/Below Basic)		-5.81%***	-0.36%	-1.02%	0.01%	-0.59%
		(1.21%)	(1.49%)	(1.54%)	(1.49%)	(1.54%)
Age Cubic Splines						
Cardiologists per 10K Residents			1.80%	1.85%	1.58%	1.71%
			(1.01%)	(1.08%)	(1.01%)	(1.08%)
Primary Care Physicians per 10K Residents			-0.07%	-0.11%	-0.03%	-0.07%
			(0.21%)	(0.21%)	(0.21%)	(0.21%)
Beds per 10K Residents			-0.01%	-0.01%	-0.01%	-0.01%
			(0.02%)	(0.02%)	(0.02%)	(0.02%)
Receives Low Income Subsidy			-4.68%**	-4.48%**	-4.65%**	-4.44%**
			(1.67%)	(1.71%)	(1.67%)	(1.70%)
Full Dual Eligible			-8.81%***	-9.37%***	-8.55%***	-9.14%***

Variables	Level	M1: Bivariate	M2: Basic Controls	M3: Basic Controls, Rural, ADI	M4: Basic Controls, Treatment Patterns	M5: Basic Controls, Rural, ADI, Treatment Patterns
			(1.98%)	(2.01%)	(1.97%)	(2.01%)
Partial Dual Eligible			-3.30%	-4.18%	-2.99%	-3.84%
			(2.17%)	(2.23%)	(2.16%)	(2.22%)
Race	White					
	Black		-4.70%**	-4.81%**	-4.45%**	-4.52%**
			(1.62%)	(1.66%)	(1.62%)	(1.66%)
	Hisp.		1.27%	1.87%	1.19%	1.78%
			(1.99%)	(2.02%)	(1.98%)	(2.02%)
	Other		-2.80%	-2.82%	-2.55%	-2.56%
			(2.21%)	(2.23%)	(2.21%)	(2.23%)
Female			3.39%***	3.16%***	3.32%***	3.09%***
			(0.77%)	(0.79%)	(0.77%)	(0.78%)
Diabetes			1.28%	1.77%*	1.29%	1.78%*
			(0.77%)	(0.78%)	(0.77%)	(0.78%)
Charlson Comorbidity Index	0					
	1		1.41%	1.48%	1.34%	1.42%
			(0.96%)	(0.98%)	(0.96%)	(0.98%)
	2		-3.15%*	-3.21%*	-3.20%*	-3.28%*
			(1.32%)	(1.34%)	(1.32%)	(1.34%)
	3		-5.36%**	-5.44%**	-5.38%**	-5.46%**
			(1.93%)	(1.96%)	(1.93%)	(1.95%)
	4+		-8.65%***	-8.87%***	-8.63%***	-8.85%***
			(2.50%)	(2.53%)	(2.49%)	(2.53%)
Year	2007					
	2008		3.33%**	3.39%**	2.17%	2.22%
			(1.13%)	(1.15%)	(1.16%)	(1.18%)
	2009		6.58%***	6.57%***	4.20%**	4.21%**
			(1.27%)	(1.29%)	(1.31%)	(1.34%)
	2010		6.43%***	6.04%***	3.32%*	2.97%*
			(1.37%)	(1.40%)	(1.43%)	(1.45%)
	2011		5.17%***	4.87%***	2.24%	1.96%
			(1.42%)	(1.45%)	(1.47%)	(1.49%)
	2012		1.47%	1.64%	-0.58%	-0.43%
			(1.41%)	(1.44%)	(1.43%)	(1.46%)
	2013		-0.99%	-1.18%	-2.98%*	-3.15%*
			(1.28%)	(1.30%)	(1.31%)	(1.34%)

Variables	Level	M1: Bivariate	M2: Basic Controls	M3: Basic Controls, Rural, ADI	M4: Basic Controls, Treatment Patterns	M5: Basic Controls, Rural, ADI, Treatment Patterns
State Fixed Effects						
Rural				-1.74%		-1.38%
				(1.04%)		(1.04%)
ADI High Deprivation				1.11%		1.00%
				(1.25%)		(1.24%)
Percent Receiving CABG					0.12%	0.12%
					(0.07%)	(0.07%)
Percent Receiving PCI					0.37%***	0.37%***
					(0.05%)	(0.05%)
			CABG			
Low Health Literacy (Basic/Below Basic)		-6.05%***	-2.98%**	-2.34%*	-2.95%**	-2.31%*
		(0.82%)	(1.11%)	(1.18%)	(1.11%)	(1.18%)
Age Cubic Splines						
Cardiologists per 10K Residents			0.14%	-0.51%	0.13%	-0.50%
			(0.80%)	(0.87%)	(0.80%)	(0.87%)
Primary Care Physicians per 10K Residents			-0.03%	-0.01%	-0.03%	-0.02%
			(0.16%)	(0.17%)	(0.16%)	(0.17%)
Beds per 10K Residents			-0.02%	-0.01%	-0.02%	-0.01%
			(0.01%)	(0.01%)	(0.01%)	(0.01%)
Receives Low Income Subsidy			-1.73%	-1.43%	-1.74%	-1.44%
			(1.33%)	(1.36%)	(1.33%)	(1.36%)
Full Dual Eligible			-6.55%***	-6.62%***	-6.50%***	-6.57%***
			(1.63%)	(1.65%)	(1.62%)	(1.65%)
Partial Dual Eligible			-0.74%	-0.73%	-0.80%	-0.77%
			(1.73%)	(1.77%)	(1.73%)	(1.77%)
Race	White			Reference		
	Black		-5.55%***	-5.68%***	-5.55%***	-5.68%***
			(1.16%)	(1.17%)	(1.16%)	(1.17%)
	Hisp.		5.38%**	4.93%**	5.38%**	4.95%**
			(1.77%)	(1.78%)	(1.77%)	(1.78%)
	Other		-0.21%	-0.66%	-0.10%	-0.55%
			(1.73%)	(1.72%)	(1.74%)	(1.73%)
Female			9.05%***	8.94%***	9.06%***	8.96%***
			(0.59%)	(0.60%)	(0.59%)	(0.60%)
Diabetes			3.49%***	3.40%***	3.49%***	3.41%***
			(0.59%)	(0.60%)	(0.59%)	(0.60%)

Variables	Level	M1: Bivariate	M2: Basic Controls	M3: Basic Controls, Rural, ADI	M4: Basic Controls, Treatment Patterns	M5: Basic Controls, Rural, ADI, Treatment Patterns
Charlson Comorbidity Index	0			Reference		
	1		0.66%	0.36%	0.66%	0.35%
			(0.75%)	(0.76%)	(0.75%)	(0.76%)
	2		1.51%	1.69%	1.51%	1.68%
			(1.07%)	(1.09%)	(1.07%)	(1.09%)
	3		-1.11%	-0.84%	-1.10%	-0.82%
			(1.52%)	(1.55%)	(1.52%)	(1.55%)
	4+		-5.61%**	-5.17%**	-5.57%**	-5.13%**
			(1.78%)	(1.83%)	(1.79%)	(1.83%)
Year	2007			Reference		
	2008		-0.66%	-0.71%	-0.94%	-1.00%
			(0.88%)	(0.89%)	(0.89%)	(0.91%)
	2009		0.95%	0.53%	0.64%	0.17%
			(0.99%)	(1.01%)	(1.03%)	(1.04%)
	2010		1.63%	1.97%	1.33%	1.59%
			(1.08%)	(1.10%)	(1.13%)	(1.16%)
	2011		0.59%	0.26%	0.29%	-0.09%
			(1.11%)	(1.12%)	(1.15%)	(1.17%)
	2012		-0.59%	-0.64%	-0.83%	-0.90%
			(1.09%)	(1.11%)	(1.11%)	(1.13%)
	2013		-3.71%***	-3.73%***	-4.00%***	-4.06%***
			(0.95%)	(0.97%)	(0.98%)	(1.00%)
State Fixed Effects						
Rural				-1.70%*		-1.71%*
				(0.78%)		(0.78%)
ADI High Deprivation				-1.21%		-1.17%
				(0.95%)		(0.96%)
Percent Receiving CABG					0.16%**	0.16%**
					(0.05%)	(0.06%)
Percent Receiving PCI					-0.01%	-0.01%
					(0.04%)	(0.04%)
Observations		15,435	15,435	14,835	15,435	14,835

Standard errors in parentheses. *** p<0.001, ** p<0.01, * p<0.05.

Appendix Table 8. Marginal Effects for Logistic Regression with Quartile Specification of Health Literacy Variable

Variables		Basic Controls ME (SE)	Basic Controls, Rural, ADI, Treatment Patterns ME (SE)
Health Literacy Quartiles	Q1 (Low HL)	-5.37%***	-2.88%
		(1.33%)	(1.52%)
	Q2	-3.70%***	-3.23%*
		(1.07%)	(1.52%)
	Q3	-3.25%**	-2.19%
		(1.05%)	(1.21%)
	Q4 (High HL)	Reference	Reference
Rural & ADI			✓
HRR PCI & CABG percentages			✓
Observations		15,435	14,835

Standard errors in parentheses. *** p<0.001, ** p<0.01, * p<0.05.

Note: The marginal effects are with respect to probability of receiving a procedure (PCI or CABG).

Appendix Table 9. Marginal Effects for Logistic Regression of Treatment with Dichotomous Specification of Health Literacy Variable

	Basic Controls	Basic Controls, Rural, ADI, Treatment Patterns
Variables	**ME (SE)**	**ME (SE)**
Low Health Literacy (Basic/Below Basic)	-3.39%*	-2.88%
	(1.46%)	(1.52%)
Rural		-3.16%**
		(1.04%)
ADI High Deprivation		-0.40%
		(1.22%)
HRR PCI & CABG percentages		✓
Observations	15,435	14,835

Standard errors in parentheses. *** p<0.001, ** p<0.01, * p<0.05.
Note: The marginal effects are with respect to probability of receiving a procedure (PCI or CABG).

APPENDIX 2. APPENDIX TABLES FOR CHAPTER 3

Appendix Table 10. Engagement Measures

Measure	Definition
1. OPTION12 Scale	The OPTION12 is a twelve-item scale that measures the degree to which clinicians involve patients in medical decision-making. The items are scored 0-4 as follows: no effort (0), minimal effort (1), some effort (2), skilled effort (3), and exemplary effort (4). The items are: 1. The clinician draws attention to an identified problem as one that requires a decision-making process 2. The clinician states that there is more than one way to deal with the identified problem (‘equipoise’) 3. The clinician assesses the patient's preferred approach to receiving information to assist decision making 4. The clinician lists ‘options’, which can include the choice of ‘no action’ 5. The clinician explains the pros and cons of options to the patient (taking ‘no action’ is an option) 6. The clinician explores the patient's expectations (or ideas) about how the problem(s) are to be managed 7. The clinician explores the patient's concerns (fears) about how problem(s) are to be managed 8. The clinician checks that the patient has understood the information 9. The clinician offers the patient explicit opportunities to ask questions during the decision-making process 10. The clinician elicits the patient's preferred level of involvement in decision making 11. The clinician indicates the need for a decision-making (or deferring) stage 12. The clinician indicates the need to review the decision (or deferment
2. Patient Questions	The total number of questions will be counted. In addition, each question will be categorized using the following criteria: 1. Was the question clarifying previous information or bringing up a new topic? 2. Was the question prompted by the clinician? 3. Was the question open ended or closed? 4. Was the question asked by a caregiver or family member? The total number of questions will be the main measure. Sensitivity analyses will be performed using each of the four sub-categories (new topic questions, unprompted questions, open ended questions, and whether asked by a caregiver or family member).

Measure	Definition
3. Patient Expressed Preferences	The total number of times a patient expressed their preferences will be counted. In addition, each expression of preference will be categorized using the following criteria: 1. Did the patient provide a rationale for their preference or did they just simply state their preference? 2. Was the expression of preference prompted by the clinician? 3. Was the patient pressured to express the preference by the clinician? For example, the clinician might ask a leading question about the patient's preferences. The total number of expressions of preferences will be the main measure. Sensitivity analyses will be performed using each of the four sub-categories (expressions with rationale, unprompted expressions, unpressured expressions of preferences, and whether expressed by a caregiver or family member).
4. Length of Discussion	The total length of the patient-clinician discussion will be recorded.

Appendix Table 11. Outcome Measures

Measure	Definition (From Patient Post Questionnaire)
1. Treatment Selection	**ITEM 1:** Which of the following best describes your current treatment plan for your stable coronary artery disease? • Medicines alone • Medicines plus stents • Other, please specify
2. Patient Knowledge	**ITEM 2:** Please respond to the following statements as best you can. [Responses: True, False, or Unsure] a. Getting a stent for stable coronary artery disease will reduce my risk of myocardial infarction or death when compared to medicines alone. b. At 1 month, there is no symptom improvement with medicines alone. c. At 1 month, more patients who got stents felt better when compared to patients on medicines alone d. At 1 year, patients on medicines alone feel about the same when compared to patients who got stents e. The added symptom relief with stents compared to medicines alone gets smaller over time f. There is a risk of having a myocardial infarction with the stent procedure itself g. Patients getting a stent can suffer more bleeding than patients on medicines alone. h. Stents eliminate symptoms of angina in all patients i. In 100 people who initially choose medicines alone, more than half will go on to need a stent during the next year j. In 100 people who initially choose a stent, 7 will need another procedure for stable coronary artery disease during the next year The total score for this outcome is the number of questions answered correctly.
3. Patient Perceived Understanding	**ITEM 2:** Thinking about the conversation that you had with your clinician today about stents plus medicines vers medicines alone for stable coronary artery disease, please mark the response that best describes your agreement with the following statements. [Responses Are: 1) Strongly Agree, 2) Agree, 3) Neither Agree Nor Disagree, 4) Disagree, and 5) Strongly Disagree] a. I know which options are available to me b. I know the benefits of each option c. I know the risks and side effects of each Each of the questions will be assessed independently since they relate to different aspects of treatment and the information for some aspects may be more difficult to understand than others.

Measure	Definition (From Patient Post Questionnaire)
4. Patient Satisfaction	**ITEM 3:** Thinking about the conversation that you had with your clinician today about stents plus medicines versus medicines alone for stable coronary artery disease, please mark the response that best describes your agreement with the following statements. [Responses Are: 1) Strongly Agree, 2) Agree, 3) Neither Agree Nor Disagree, 4) Disagree, and 5) Strongly Disagree] a. I am clear about which benefits matter most to me b. I am clear about which risks and side effects matter most to me c. I have enough support from others to make a choice d. I am choosing without pressure from others e. I have enough advice to make a choice f. I am clear about the best choice for me g. I feel sure about what to choose h. This decision is easy for me to make i. I feel I have made an informed choice j. My decision shows what is important to me k. I expect to stick with my decision l. I am satisfied with my decision **ITEM 5:** How would you describe the clarity of information about stents plus medicines versus medicines alone for stable coronary artery disease given during this visit? [Responses Are: 1-7 from 1 “Too Little Information” to 7 “Too much Information”] An overall patient satisfaction score will be created by summing the number of elements in Item 3 for which the patient responded “Strongly Agree” or “Agree.” Item 5 will be analyzed separately from the total patient satisfaction score.

Appendix Table 12. Health Literacy Measure

Measure	Definition (From Patient Pre Questionnaire)
Health Literacy	**ITEMS 8:** How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read hospital materials? 1) All of the time 2) Most of the time 3) Some of the time 4) A little of the time 5) None of the Time **ITEM 9:** How often do you have problems learning about your medical condition because of difficulty understanding written information? [Same responses as above] **ITEM 10:** How confident are you filling out healthcare forms by yourself? 1) Extremely 2) Quite a bit 3) Somewhat 4) A little bit 5) Not at all

APPENDIX 3. APPENDIX TABLES FOR CHAPTER 4

Appendix Table 13. Diagnostic Algorithms for Identifying Stable Angina Pectoris

Algorithm	Diagnostic Criteria	Medication Criteria
1	• 2 claims with diagnoses for stable angina pectoris	• 2 claims for nitrates for medical therapy • No claims for nitrates required for PCI or CABG
2	• 2 claims with diagnoses for coronary artery disease • 2 claims with diagnoses for chest pain	• 2 claims for nitrates for medical therapy • No claims for nitrates required for PCI or CABG

Adapted from Kempf et al. 2011. Note that medication use was not required for patients receiving PCI or CABG because receiving a procedure was considered sufficient evidence that the patient had stable angina pectoris.

Appendix Table 14. International Classification of Diseases, Ninth Revision

Diagnosis	ICD-9 Codes
Stable angina pectoris	413.0, 413.1, 413.9
Coronary artery disease	411.0, 411.1, 411.8, 411.81, 411.89, 414.00, 414.01, 414.02, 414.03, 414.04, 414.05, 414.06, 414.07, 414.10, 414.11, 414.12, 414.19, 414.2, 414.3, 414.8, 414.9, 429.2, 429.6, 429.71, 429.79, 996.03, V45.81, V45.82
Chest pain	786.51, 785.52, 786.59
Myocardial infarction	410.0, 410.1, 410.2, 410.3, 410.4, 410.5, 410.6, 410.7, 410.8, 410.00, 410.01, 410.02, 410.10, 410.11, 410.12, 410.20, 410.21, 410.22, 410.30, 410.31, 410.32, 410.40, 410.41, 410.42, 410.50, 410.51, 410.52, 410.60, 410.61, 410.62, 410.70, 410.71, 410.72, 410.80, 410.81, 410.82, 410.90, 410.91, 410.92, 412"
Unstable angina pectoris	411.1
Diabetes	249.01, 249.10, 249.11, 249.20, 249.21, 249.30, 249.31, 249.40, 249.41, 249.50, 249.51, 249.60, 249.61, 249.70, 249.71, 249.80, 249.81, 249.90, 249.91, 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93

Appendix Table 15. Procedural Codes

Procedure	Code Type	Codes
PCI	CPT (pre 2013)	92980, 92981, 92982, 92983, 92984, 92995, 92996
	CPT (post 2013)	92920, 92921, 92924, 92925, 92928, 92929, 92933, 92934, 92937, 92938
	ICD-9 Procedure	00.66, 36.06, 36.01, 36.02, 36.05, 36.09
	DRG (pre 2008)	518, 555, 556, 557, 558
	DRG (post 2008)	246, 247, 248, 249, 250, 251
CABG	CPT	33510, 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33520, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536
	ICD-9 Procedure	36.1, 36.10, 36.11, 36.12, 36.13, 36.14, 36.15, 36.16, 36.17, 36.19
	DRG (pre 2008)	106, 547, 548, 549, 550
	DRG (post 2008)	231, 232, 233, 234, 235, 236

Note: CABG stands for coronary artery bypass graft surgery, CPT stands for current procedural terminology, DRG stands for diagnosis related group, PCI stands for percutaneous coronary intervention.

Appendix Table 16. Standardized Differences Before and After IPTW for Binary Health Literacy

		Unweighted			Weighted		
Variable	Level	CABG	Med. Only	Std. Diff.	CABG	Med. Only	Std. Diff.
Health Literacy	Basic/Below Basic	6.4%	11.9%	0.18	8.6%	10.8%	0.069
Age		73.4	76.9	0.46	75.0	75.9	0.12
Cardiologists per 10K		0.7	0.7	0.04	0.6	0.7	0.05
PCPs per 10K		7.0	7.2	0.05	7.0	7.1	0.05
Beds per 10K		33.3	34.2	0.03	32.2	34.0	0.07
Low Income Subsidy		0.2	0.3	0.36	25.4%	30.1%	0.10
Dual Eligible		9.2%	22.3%	0.34	14.4%	18.7%	0.11
Partial Dual Eligible		4.8%	7.1%	0.10	5.6%	6.5%	0.04
RTI Race	Black	3.6%	9.2%	0.21	5.7%	8.0%	0.08
RTI Race	Hispanic	5.6%	5.5%	0.01	5.4%	5.3%	0.00
RTI Race	Other	3.8%	4.0%	0.01	4.2%	3.8%	0.02
Female		67.9%	35.6%	0.66	47.5%	42.4%	0.10
Diabetes		49.0%	38.1%	0.22	42.3%	40.6%	0.04
Charlson Comorbidity Index	One	19.2%	20.0%	0.02	19.4%	19.6%	0.01
	Two	9.3%	9.2%	0.00	8.7%	8.9%	0.01
	Three	3.0%	4.3%	0.07	3.0%	3.8%	0.04
	Four	1.0%	2.5%	0.10	1.0%	2.1%	0.08
Year	2008	17.8%	17.9%	0.00	17.8%	17.8%	0.00
	2009	14.7%	12.2%	0.07	14.1%	12.8%	0.04
	2010	11.7%	9.6%	0.07	11.8%	10.2%	0.05
	2011	10.8%	9.0%	0.06	9.6%	9.3%	0.01
	2012	9.5%	9.3%	0.01	8.9%	9.5%	0.02
	2013	11.2%	13.5%	0.07	12.0%	13.1%	0.03
ADI Category	High Deprivation	11.3%	13.9%	0.08	11.8%	13.4%	0.05
Rural		25.7%	25.4%	0.01	26.0%	25.8%	0.00
		CABG	PCI	Std. Diff.	CABG	PCI	Std. Diff.
Health Literacy	Basic/Below Basic	6.4%	8.9%	0.08	8.6%	10.1%	0.05
Age		73.4	73.8	0.06	75.0	75.3	0.04
Cardiologists per 10K		0.7	0.7	0.03	0.6	0.7	0.05
PCPs per 10K		7.0	7.1	0.01	7.0	7.1	0.03
Beds per 10K		33.3	34.1	0.03	32.2	33.6	0.05
Low Income Subsidy		18.4%	21.2%	0.06	25.4%	27.9%	0.05
Dual Eligible		9.2%	11.1%	0.05	14.4%	16.6%	0.06
Partial Dual Eligible		4.8%	5.6%	0.03	5.6%	6.1%	0.02
RTI Race	Black	3.6%	5.8%	0.08	5.7%	7.1%	0.06
RTI Race	Hispanic	5.6%	5.0%	0.03	5.4%	5.7%	0.01
RTI Race	Other	3.8%	2.8%	0.06	4.2%	3.3%	0.05
Female		67.9%	53.6%	0.29	47.5%	44.9%	0.05
Diabetes		49.0%	45.1%	0.08	42.3%	42.7%	0.01
Charlson Comorbidity Index	One	19.2%	19.5%	0.01	19.4%	20.3%	0.02
	Two	9.3%	8.5%	0.03	8.7%	8.9%	0.01

	Three	3.0%	2.8%	0.01	3.0%	3.2%	0.01
	Four	1.0%	1.4%	0.03	1.0%	1.7%	0.05
Year	2008	17.8%	18.1%	0.01	17.8%	18.4%	0.02
	2009	14.7%	14.6%	0.00	14.1%	13.5%	0.02
	2010	11.7%	12.2%	0.02	11.8%	10.7%	0.04
	2011	10.8%	10.4%	0.02	9.6%	9.8%	0.01
	2012	9.5%	9.3%	0.01	8.9%	9.4%	0.02
	2013	11.2%	12.2%	0.03	12.0%	12.5%	0.01
ADI Category	High Deprivation	11.3%	13.3%	0.06	11.8%	13.7%	0.06
Rural		25.7%	26.2%	0.01	26.0%	25.2%	0.02

		Med. Only	PCI	Std. Diff.	Med. Only	PCI	Std. Diff.
Health Literacy	Basic/Below Basic	11.9%	8.9%	0.09	10.8%	10.1%	0.02
Age		76.9	73.8	0.40	75.9	75.3	0.08
Cardiologists per 10K		0.7	0.7	0.01	0.7	0.7	0.00
PCPs per 10K		7.2	7.1	0.04	7.1	7.1	0.01
Beds per 10K		34.2	34.1	0.00	34.0	33.6	0.01
Low Income Subsidy		0.3	0.2	0.30	0.3	0.3	0.05
Dual Eligible		0.2	0.1	0.29	0.2	0.2	0.06
Partial Dual Eligible		0.1	0.1	0.06	0.1	0.1	0.02
RTI Race	Black	9.2%	5.8%	0.13	8.0%	7.1%	0.03
RTI Race	Hispanic	5.5%	5.0%	0.02	5.3%	5.7%	0.02
RTI Race	Other	4.0%	2.8%	0.06	3.8%	3.3%	0.02
Female		35.6%	53.6%	0.37	42.4%	44.9%	0.05
Diabetes		38.1%	45.1%	0.14	40.6%	42.7%	0.04
Charlson Comorbidity Index	One	20.0%	19.5%	0.01	19.6%	20.3%	0.02
	Two	9.2%	8.5%	0.02	8.9%	8.9%	0.00
	Three	4.3%	2.8%	0.08	3.8%	3.2%	0.03
	Four	2.5%	1.4%	0.08	2.1%	1.7%	0.03
Year	2008	17.9%	18.1%	0.01	17.8%	18.4%	0.01
	2009	12.2%	14.6%	0.07	12.8%	13.5%	0.02
	2010	9.6%	12.2%	0.08	10.2%	10.7%	0.02
	2011	9.0%	10.4%	0.05	9.3%	9.8%	0.02
	2012	9.3%	9.3%	0.00	9.5%	9.4%	0.00
	2013	13.5%	12.2%	0.04	13.1%	12.5%	0.02
ADI Category	High Deprivation	13.9%	13.3%	0.02	13.4%	13.7%	0.01
Rural		25.4%	26.2%	0.02	25.8%	25.2%	0.01

Appendix Table 17. Descriptive Statistics by Health Literacy Category

Categorical Variables	Level	Low Health Literacy Area (N=1,890)	High Health Literacy Area (N=15,626)	Overall (N=17,516)
Adherent (PDC>80%) First Six Months Following Diagnosis	Adherent	1,409 (74.6%)	12,379 (79.2%)	13,788 (78.7%)
	Non-Adherent	481 (25.4%)	3,247 (20.8%)	3,728 (21.3%)
Adherent (PDC>80%) Second Six Months Following Diagnosis	Adherent	1,149 (60.8%)	10,582 (67.7%)	11,731 (67.0%)
	Non-Adherent	741 (39.2%)	5,044 (32.3%)	5,785 (33.0%)
First Treatment Received	Medication Only	1,428 (75.6%)	10,474 (67.0%)	11,902 (67.9%)
	PCI	351 (18.6%)	3,573 (22.9%)	3,924 (22.4%)
	CABG	111 (5.9%)	1,579 (10.1%)	1,690 (9.6%)
Sex	Male	1,227 (64.9%)	8,798 (56.3%)	10,025 (57.2%)
	Female	663 (35.1%)	6,828 (43.7%)	7,491 (42.8%)
Age	65-70	579 (30.6%)	4,060 (26.0%)	4,639 (26.5%)
	70-75	424 (22.4%)	3,431 (22.0%)	3,855 (22.0%)
	75-80	356 (18.8%)	3,002 (19.2%)	3,358 (19.2%)
	80+	531 (28.1%)	5,133 (32.8%)	5,664 (32.3%)
RTI Race	White	559 (29.6%)	13,960 (89.3%)	14,519 (82.9%)
	Black	745 (39.4%)	635 (4.1%)	1,380 (7.9%)
	Hispanic	472 (25.0%)	483 (3.1%)	955 (5.5%)
	Other	114 (6.0%)	548 (3.5%)	662 (3.8%)
Diabetes	No	907 (48.0%)	9,475 (60.6%)	10,382 (59.3%)
	Yes	983 (52.0%)	6,151 (39.4%)	7,134 (40.7%)
Charlson Comorbidity Index	0	1,102 (58.3%)	10,316 (66.0%)	11,418 (65.2%)
	1	403 (21.3%)	3,072 (19.7%)	3,475 (19.8%)
	2	215 (11.4%)	1,373 (8.8%)	1,588 (9.1%)
	3	117 (6.2%)	551 (3.5%)	668 (3.8%)
	4+	53 (2.8%)	314 (2.0%)	367 (2.1%)
Year	2007	618 (32.7%)	4,085 (26.1%)	4,703 (26.8%)
	2008	354 (18.7%)	2,809 (18.0%)	3,163 (18.1%)
	2009	237 (12.5%)	2,049 (13.1%)	2,286 (13.1%)
	2010	210 (11.1%)	1,593 (10.2%)	1,803 (10.3%)
	2011	159 (8.4%)	1,504 (9.6%)	1,663 (9.5%)
	2012	134 (7.1%)	1,495 (9.6%)	1,629 (9.3%)
	2013	178 (9.4%)	2,091 (13.4%)	2,269 (13.0%)
Area Deprivation Index Category	Low Deprivation	1,028 (54.4%)	14,020 (89.7%)	15,048 (85.9%)
	High Deprivation	862 (45.6%)	1,606 (10.3%)	2,468 (14.1%)
Rural Status	Urban	1,597 (84.5%)	11,601 (74.2%)	13,198 (75.3%)
	Rural	293 (15.5%)	4,025 (25.8%)	4,318 (24.7%)
Continuous Variables		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Cardiologists per 10K		0.79 (0.56)	0.67 (0.60)	0.68 (0.60)
PCPs per 10K		7.06 (2.49)	7.21 (2.90)	7.19 (2.86)
Beds per 10K		38.09 (26.30)	33.53 (26.78)	34.02 (26.77)
Full Dual Eligible*		45.0% (48.6%)	15.4% (35.3%)	18.6% (38.1%)
Partial Dual Eligible*		10.8% (29.6%)	5.9% (22.5%)	6.4% (23.4%)
Receives Low Income Subsidy*		63.9% (47.6%)	25.8% (43.4%)	29.9% (45.4%)
Area-Level Measure of Pct. Receiving PCI		21.5% (6.6%)	22.1% (7.1%)	22.1% (7.1%)
Area-Level Measure of Pct. Receiving CABG		9.0% (4.0%)	9.3% (4.3%)	9.3% (4.3%)

Appendix Table 18. Regression Output Using Quartile Health Literacy Measure

Variable	Level	Probit Regression with Basic Controls	Probit Regression with ADI & Rural	IPTW with Basic Controls	IPTW with ADI & Rural	2SRI with Basic Controls	2SRI with ADI & Rural
		ME (SE)	ME (SE)	ME (SE)	ME (SE)	ME (SE)	ME (SE)
Health Literacy Quartile	Q1	-2.61%** (1%)	-3.07%** (1.11%)	-3.21%** (1.23%)	-4.55%** (1.65%)	-2.34%* (1.05%)	-2.78%* (1.13%)
	Q2	-0.7% (0.81%)	-1.22% (0.89%)	-0.5% (1.01%)	-1.36% (1.35%)	-0.6% (0.87%)	-1.17% (0.95%)
	Q3	-0.41% (0.81%)	-0.9% (0.85%)	0.56% (1%)	-0.19% (1.29%)	-0.3% (0.83%)	-0.82% (0.9%)
	Q4	Reference					
Med. Only		Reference					
CABG		-2.61%** (1%)	-3.07%** (1.11%)	-3.21%** (1.23%)	-4.55%** (1.65%)	18.55%* (8.12%)	17.99%* (8.91%)
PCI		-0.7% (0.81%)	-1.22% (0.89%)	-0.5% (1.01%)	-1.36% (1.35%)	-3.06% (8.95%)	-2.46% (9.06%)
Cardiologists per 10K		0.0004 (0.0071)	0.0089 (0.0076)	-0.0024 (0.0082)	0.0035 (0.011)	0.0004 (0.0074)	0.0089 (0.0077)
PCPs per 10K		0.0019 (0.0015)	0.0018 (0.0015)	0.0008 (0.0017)	0.0013 (0.0022)	0.0024 (0.0016)	0.0022 (0.0017)
Beds per 10K		-0.0001 (0.0001)	-0.0002 (0.0001)	-0.0001 (0.0001)	-0.0002 (0.0002)	-0.0001 (0.0001)	-0.0002 (0.0001)
Low Income Subsidy		2.64% (1.24%)	0.32% (1.27%)	0.54% (1.54%)	0.76% (1.97%)	0.66% (1.29%)	0.73% (1.33%)
Dual Eligible		-0.69% (1.38%)	-0.8% (1.41%)	-1.8% (1.85%)	-2.43% (2.34%)	0.27% (1.47%)	0.13% (1.52%)
Partial Dual Eligible		-1.15% (1.58%)	-1.36% (1.62%)	-0.49% (1.95%)	-0.73% (2.56%)	-0.78% (1.62%)	-1.06% (1.57%)
Race	White	Reference					
	Black	-4.23%** (1.22%)	-3.77%** (1.25%)	-0.98% (1.61%)	-0.44% (1.9%)	-3.31%** (1.27%)	-2.85%* (1.4%)
	Hispanic	-8.88%*** (1.48%)	-8.16%*** (1.51%)	-5.91%** (1.7%)	-5.39%* (2.16%)	-9.44%*** (1.51%)	-8.7%*** (1.62%)
	Other	-3.08% (1.63%)	-2.34% (1.66%)	-3.49% (2.38%)	-1.66% (2.99%)	-3.48%* (1.75%)	-2.64% (1.63%)
Female		-3.19%*** (0.61%)	-3.06%*** (0.62%)	-2.85%*** (0.72%)	-2.37%** (0.88%)	-5.43%*** (1.19%)	-5.21%*** (1.23%)
Diabetes		2.4%*** (0.59%)	2.51%*** (0.6%)	1.17% (0.72%)	1.3% (0.88%)	1.59%* (0.73%)	1.71%* (0.77%)
Charlson Comorbidity Index	0	Reference					
	1	-1.06% (0.74%)	-1.21% (0.76%)	-0.03% (0.92%)	0.1% (1.12%)	-1.26% (0.77%)	-1.36% (0.8%)
	2	0.63% (1%)	0.39% (1.02%)	-1.57% (1.33%)	-2.05% (1.7%)	0.28% (1.07%)	0.01% (1.11%)
	3	2.58% (1.42%)	2.2% (1.45%)	1.06% (1.92%)	0.81% (2.11%)	2.61% (1.4%)	2.2% (1.45%)
	4+	0.51% (1.98%)	0.15% (2.02%)	1% (2.6%)	0.01% (3.43%)	1.28% (1.99%)	0.85% (1.89%)
Year	2007	Reference					
	2008	-0.72% (0.89%)	-0.44% (0.9%)	0.57% (1.08%)	0.51% (1.35%)	-0.81% (0.97%)	-0.56% (0.95%)
	2009	0.44% (0.98%)	0.38% (1%)	2.14% (1.24%)	1.38% (1.58%)	0.12% (1.04%)	0.11% (1.08%)
	2010	-0.01% (1.06%)	0.57% (1.08%)	-0.44% (1.42%)	-0.26% (1.72%)	-0.26% (1.21%)	0.21% (1.24%)
	2011	1.44% (1.08%)	1.66% (1.1%)	2.34% (1.29%)	1.99% (1.59%)	1.25% (1.2%)	1.51% (1.09%)
	2012	5.34%*** (1.05%)	4.97%*** (1.08%)	4.98%*** (1.33%)	4.08%* (1.58%)	5.43%*** (1.12%)	5.03%*** (1.13%)
	2013	6.12%*** (0.95%)	6.44%*** (0.97%)	6.94%*** (1.15%)	6.98%*** (1.43%)	6.63%*** (0.96%)	6.92%*** (0.98%)
Rural			1.83%* (0.79%)		0.84% (1.21%)		1.96%* (0.78%)

Variable	Level	Probit Regression with Basic Controls	Probit Regression with ADI & Rural	IPTW with Basic Controls	IPTW with ADI & Rural	2SRI with Basic Controls	2SRI with ADI & Rural
		ME (SE)	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**	**ME (SE)**
ADI Quartiles	Q1	Reference					
	Q2		1.22% (0.85%)		3.62%** (1.3%)		1.45% (0.91%)
	Q3		1.47% (0.94%)		2.54% (1.45%)		1.52% (0.97%)
	Q4		0.17% (1.07%)		2.55% (1.62%)		0.14% (1.15%)
Period		11.76%*** (0.32%)	11.75%*** (0.32%)	12.17%*** (0.71%)	12.2%*** (0.53%)	11.76%*** (0.3%)	11.75%*** (0.33%)

Note: ME stands for marginal effect, SE stands for standard error, IPTW stands for inverse probability of treatment weighting, 2SRI stands for two-stage residual inclusion, CABG stands for coronary artery bypass grafting, PCI stands for percutaneous coronary

Appendix Table 19. Marginal Effects for Alternative Residual Specifications with Binary Health Literacy

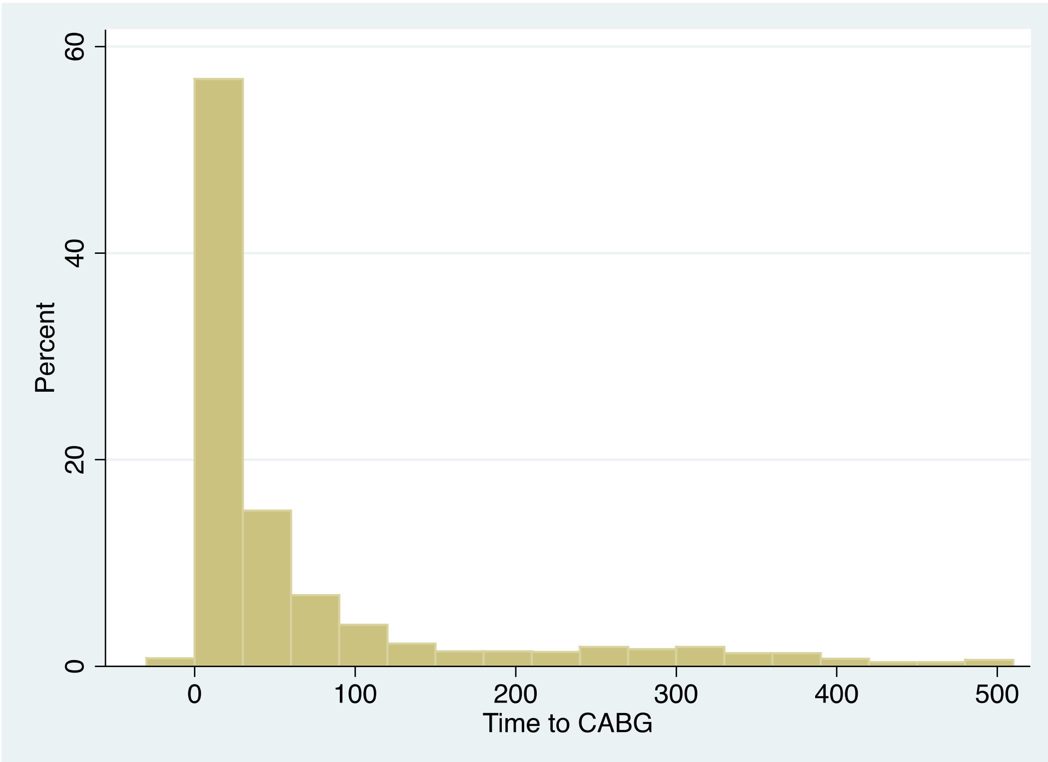
	Raw Residuals		Standardized Residuals		Deviance Residuals	
	ME	**SE**	**ME**	**SE**	**ME**	**SE**
Low HL	-0.89%	1.33%	-1.49%	1.27%	-1.07%	1.31%
CABG	20.07%**	7.98%	-1.29%	2.94%	14.07%	9.07%
PCI	-5.05%	9.11%	0.52%	3.94%	-3.33%	11.05%

Appendix Table 20. Marginal Effects for Alternative Residual Specifications with Quartile Health Literacy

	Raw Residuals		Standardized Residuals		Deviance Residuals	
	ME	**SE**	**ME**	**SE**	**ME**	**SE**
Q1	2.78%*	1.27%	-3.01%*	1.17%	-2.88%*	1.24%
Q2	-1.17%	0.86%	-1.16%	0.80%	-1.19%	0.81%
Q3	-0.82%	-0.82%	-0.88%	0.74%	-0.85%	0.78%
Q4	Reference		Reference		Reference	
CABG	17.99%	-3.01%	-1.45%	3.00%	12.52%	9.96%
PCI	-2.46%	8.95%	0.24%	3.99%	-2.58%	11.22%

APPENDIX 4. APPENDIX FIGURES FOR CHAPTER 5

Appendix Figure 1. Days After Initial Diagnosis Until CABG Surgery



Appendix Figure 2. Days After Initial Diagnosis Until PCI Procedure